



**UNIVERSITAT DE LLEIDA**

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**“The effectiveness of Pelvic Floor Muscle Training  
through Immersive Virtual Reality for the treatment of  
Stress Urinary Incontinence based on the impact on the  
quality of life in adult women elite athletes”**

*- A randomized controlled trial -*

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## ACRONYM INDEX

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- **ICS:** International Continence Society
- **IUA:** International Urogynecological Association
- **UI:** Urinary Incontinence
- **PFMT:** Pelvic floor muscle training
- **ONI:** National Incontinence Observatory
- **SUI:** Stress urinary incontinence
- **BF:** Biofeedback
- **RCT:** Randomized controlled trial
- **SR:** Systematic Reviews
- **IVR:** Immersive virtual reality
- **EAU:** European Association of Urology
- **ICIQ-SF:** International Consultation on Incontinence questionnaire - short form
- **NICE:** National Institute for Health and Care Excellence
- **ISI:** Incontinence severity index
- **MVC:** Maximal voluntary contraction
- **QoL:** Quality of life
- **SPSS:** Statistical Package for the Social Sciences
- **IRB:** Institutional review board
- **EC:** Ethical committee
- **NHS:** National Health Service
- **TTP:** Train-to-play

## RESUMEN

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**Pregunta de investigación:** ¿Es eficaz el entrenamiento muscular del suelo pélvico con biofeedback mediante un programa de realidad virtual inmersiva para mejorar la calidad de vida de mujeres deportistas de élite en edad adulta?

**Objetivo:** Evaluar la efectividad del entrenamiento muscular del suelo pélvico con biofeedback mediante un programa de realidad virtual inmersiva para mejorar la calidad de vida en mujeres deportistas de élite en edad adulta.

**Metodología:** Diseño del estudio: Se diseñará un ensayo clínico controlado aleatorio de doble ciego en un número total de 64 mujeres que padecen incontinencia urinaria de esfuerzo. Muestra y aleatorización: Las participantes, atletas del *Car de Sant Cugat* en edad adulta, serán asignadas al azar y de forma equivalente; 32 participantes en el grupo control y 32 participantes en el grupo experimental. Intervención: Las pacientes serán aleatorizadas y asignadas para realizar los ejercicios de entrenamiento muscular del suelo pélvico con biofeedback y mediante un programa de realidad virtual inmersiva (grupo experimental) o para realizar los ejercicios de entrenamiento muscular del suelo pélvico con solo biofeedback (grupo de control). Mediciones: Para el objetivo principal se utilizará el ICIQ-SF (International Consultation of Incontinence Questionnaire-Short Form) para medir el impacto de la incontinencia urinaria de esfuerzo en la calidad de vida. Las medidas de los objetivos secundarios evaluarán; las fugas de orina mediante el Pad Test, la gravedad de la incontinencia urinaria mediante el cuestionario ISI (Incontinence severity index), la fuerza muscular del suelo pélvico mediante el perineometro y para medir la adherencia al tratamiento se tendrá en cuenta las veces que la paciente accede a la aplicación informática de ejercicios de rehabilitación. Calendario y evaluaciones: La intervención durará un año con una evaluación al comienzo del proceso y en los meses 3, 6 y 12.

**Palabras clave:** fisioterapia, incontinencia urinaria de esfuerzo, entrenamiento muscular del suelo pélvico, deportistas de élite, nuevas tecnologías.

## ABSTRACT

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**Research question:** Is it effective the pelvic floor muscle training with biofeedback and using an immersive virtual reality programme to improve quality of life in adult elite women athletes?

**Objective:** To evaluate the effectiveness of pelvic floor muscle training with biofeedback using an immersive virtual reality programme to improve quality of life in adult elite women athletes.

**Methods:** Study design: A double blind randomized controlled clinical trial with a total number of 64 women who suffer from stress urinary incontinence. Sample and randomization: The adult women elite athletes from *Sant Cugat CAR* will be assigned randomly and equally, 32 subjects in the control group and 32 subjects in the experimental group. Intervention: Patients will be randomly assigned either to the pelvic floor muscle training with biofeedback using an immersive virtual reality by an application programme (experimental) or to the pelvic floor muscle training with biofeedback alone by the same application programme (control). Measurements: The primary outcome will be the quality of life measured with International Consultation on Incontinence Questionnaire - Short Form. Secondary outcomes will be the urine leakage measured by Pad Test, urinary incontinence severity measured by Incontinence Severity Index test, pelvic floor muscle strength measured by perineometry and to measure the treatment adherence it will be taken into account the times that the patient accesses the application. Calendar and assessments: the intervention will last one year with evaluations at the beginning of the process and in the 3<sup>rd</sup>, 6<sup>th</sup> and 12<sup>th</sup> month.

**Key words:** physiotherapy, stress urinary incontinence, pelvic floor muscle training, elite athletes, new technologies.



## INTRODUCTION

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The International Continence Society (ICS) and the International Urogynecological Association (IUA) define urinary incontinence (UI) as a symptom, namely “the complaint of any involuntary loss of urine” (1).

The urinary incontinence is an underdiagnosed pathology and in many cases undertreated or not properly treated. Furthermore, not only is a medical problem but also psychosocial problems, causing a concealment because of fear to social rejection (2) and negative self-perception (3). The wide range of published prevalence of UI reflects differences in its definition, the methodology and demographics of the studies population (4). However, the prevalence figures are not exact to reflect the true incidence of this pathology since the shame and other factors may lead to inaccurate results (3).

It has been published that UI is twice as common in women as in men. While in Spain the average women prevalence is 24% in men is 7% (2). Women stop or diminish their activity and social participation (1). It has been reported that there is an association between physical exertion and urinary loss. An increase of intra-abdominal pressure due to physical exertion, leads to an increase of intra-vesical pressure and, if it is higher than intraurethral pressure, the resulting is an urine leakage. That is why many athletic women suffer from this pathology (1).

Moreover, economic costs of urinary incontinence are considerable (5), which in 1996 in Spain supposed 120 millions of euros, and that sometimes are financed by the patients and in other cases by the National Health Service (6). Furthermore, in 2015 absorbents and sanitary towels for urinary incontinence were the most important medical devices consumption in containers (7.5 million) and in amount (288.9 million euros) (7).

Nonetheless, there is no consensus on the optimum type, duration, or frequency of pelvic floor muscle training (PFMT), which is the first line of conservative treatment (8). The actual evidence is insufficient to make any robust recommendation about the best approach to PFMT (9), so it is clear the need of doing more research in this field because it will be able to provide new knowledge that will help improving the quality of life of the patients who suffer from it.

# 1 THEORICAL FRAMEWORK

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## 1.1 ANATOMY AND PHISIOLOGY

### 1.1.1 URINARY WOMEN SYSTEM

The body absorbs the nutrients to maintain every corporal function. Once the body soaks up what it needs, the urinary system synergy works with the lungs, the skin and the intestines to eliminate the residues in order to maintain a chemical and water equilibrium (10).

Urinary system comprises a series of organs, tubs muscles and nerves which work together to produce, keep and transport urine. Urinary system consists of two kidneys, two ureters, the bladder, two sphincters and the urethra (10):

- Kidneys: Located at the back of the abdomen, beside the vertebral column. Kidneys eliminate the urea through the nephrons. Urea, water and other residues conform the urine.
- Ureters: Tubular organs from the kidneys to the bladder, responsible of urine transport. They have between 8 and 10 inches of length.
- Bladder: Muscular organ situated above the pelvis, responsible to keep the urine until it is voluntary evacuated. It is formed by the detrusor muscle which is the responsible of the contraction. In normal conditions it keeps among 400cc of urine.
- Sphincters: They help keeping the urine and avoid the dripping. The intern involuntary sphincter it is formed by straight muscle and the voluntary external sphincter it is formed by stretch-marked muscle.
- Urethra: Tubular organ which communicates the bladder with the exterior allowing the urine evacuation.

### 1.1.2 REPRODUCTIVE SYSTEM

Elements: vulva (clitoris), uterus and vagina, fallopian tubes, ovaries, glands of Skene and Bartholin (11).

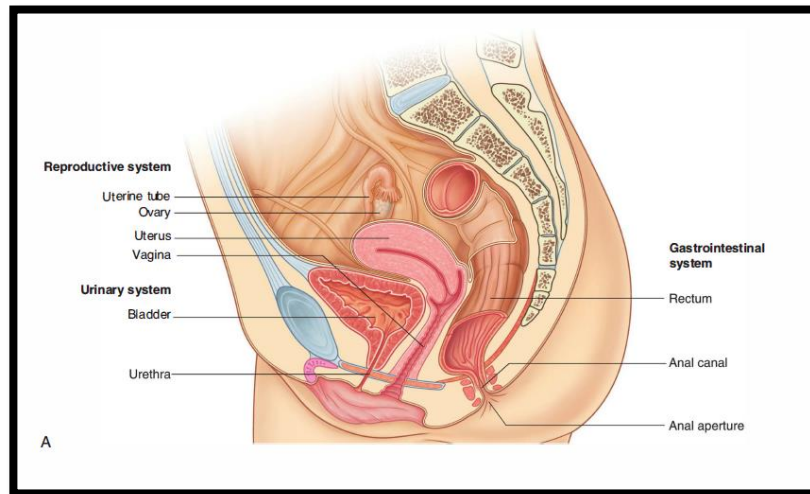


Figure 1. The pelvis and perineum contain and support terminal parts of the gastrointestinal, urinary, and reproductive systems (11).

### 1.1.3 INNERVATION CONTROL OF THE URINATION

<b>Sympathetic nucleus</b>	Hypogastric nerve (D10-L1)	Internal sphincter
<b>Parasympathetic nucleus</b>	Pelvic nerve (S2-S3-S4)	Detrusor
<b>Somatic nucleus</b>	Pudendal nerve (S3-S4)	External sphincter

Table 1. Innervation control of the urination (11).

### 1.1.4 URINATE PHYSIOLOGY (12)

The micturition is defined as: *the bladder emptying when it fills full of its physiology capacity.*

Conditions for a normal micturition:

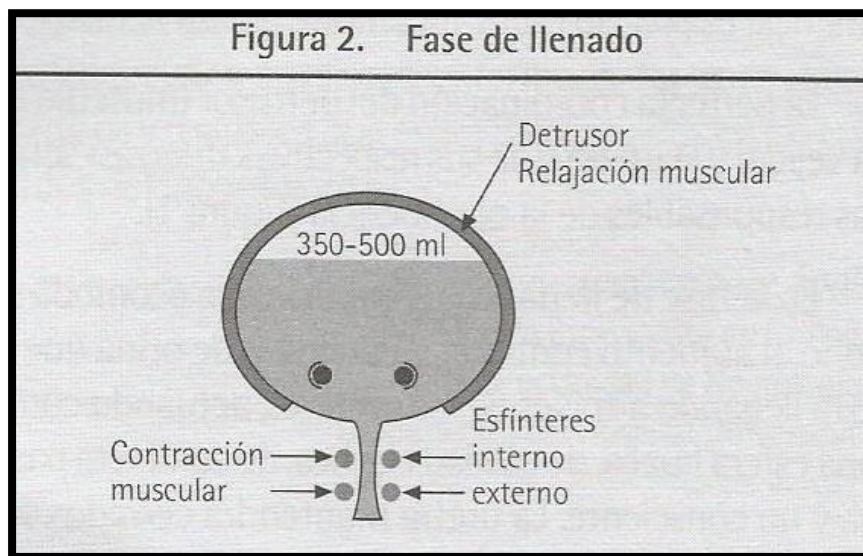
- ✓ Voluntary
- ✓ Complete
- ✓ No pain
- ✓ Capacity to interrupt
- ✓ Separated > 2 hours
- ✓ Without urgency
- ✓ Occasionally

It consists of two phases: fill phase and empty phase

➤ FILL PHASE:

- Bladder relaxation
- Detrusor relaxation
- Internal sphincter (involuntary) in contraction
- External sphincter (voluntary) in contraction

To be continent during the filling phase the urethral pressure (UP) has to be > than the vesical pressure (VP)



*Figure 2. Urethral pressure and Vesical pressure during the filling urination phase (12).*

➤ EMPTY PHASE:

- Detrusor contraction
- Internal sphincter relaxation
- External sphincter relaxation

During the emptying phase  $UP < VP$  [**Voluntary micturition:  $UP - VP = +$** ]

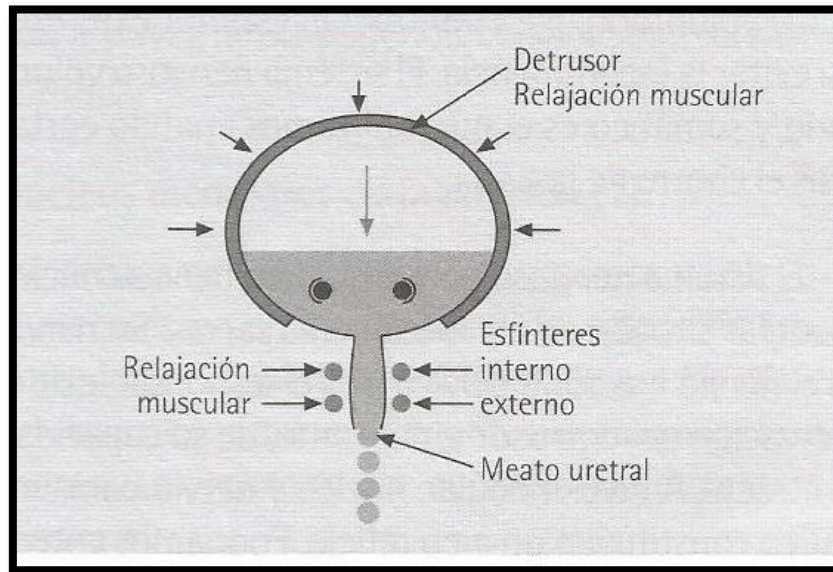


Figure 3. Urethral pressure and vesical pressure during emptying urination phase (12).

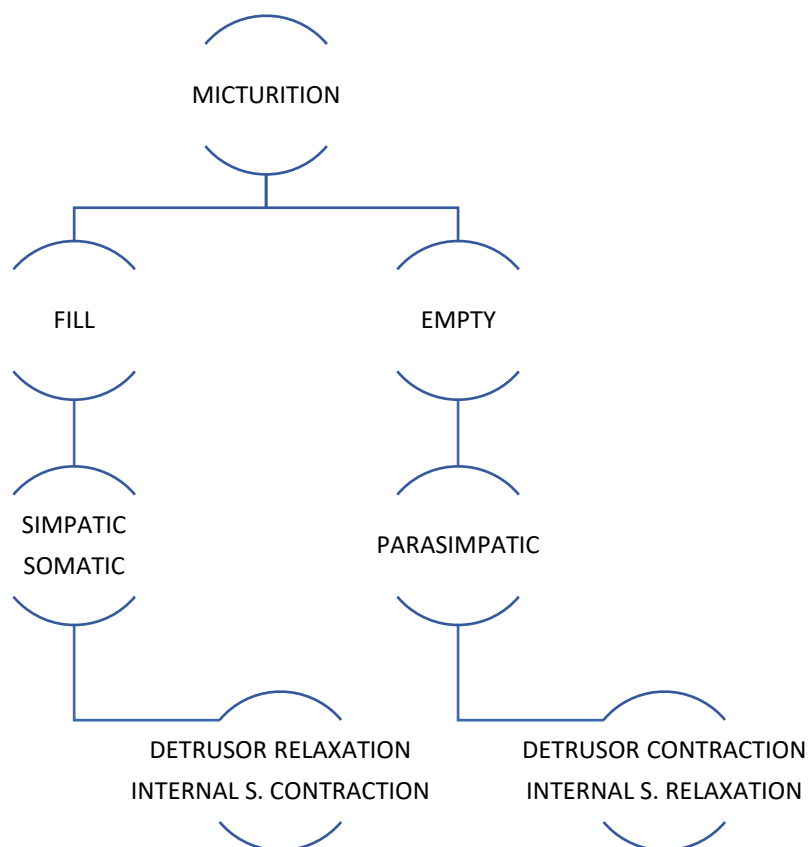


Figure 4. Bladder filling and emptying diagram.

### 1.1.5 FEMALE PELVIC FLOOR ANATOMY

#### 1.1.5.1 LIGAMENTS STRUCTURE

The most important ligaments are (13):

- a) Pubourethrals: They have its origin in the low rim of the pubis. They are inserted sideways in pelvic fascia arch at the level of the average third of the urethra.
- b) Urethro-pelvics: They have its origin sideways in the pubourethral ligaments and they are inserted in the central region, being the main suburethral support. They act as a whole with the pubourethral ligaments in the mechanisms of continence and micturition.
- c) Uterosacrals: They have its origin sideways in the front of the sacrum and they are inserted in fascia pubocervical in the vaginal apex.

The region between the pubourethral ligaments and the vesical neck is named the area of critical elasticity for its dynamic and fundamental role in the micturition mechanism and of urinary continence.

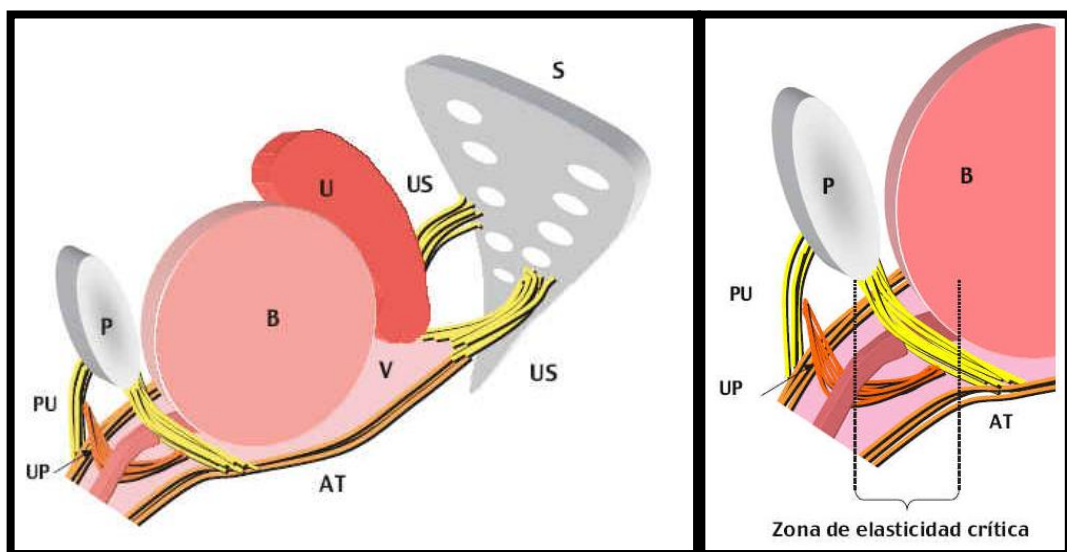


Figure 5. Ligaments structure: P: pubis; U: uterus; V: vagina; S: sacrum; AT: tendinous arch; PU: pubourethral ligament; UP: urethro-pelvic ligament; US: uterosacral (13).

### 1.1.5.2 PERINEAL MUSCULAR SYSTEM (ACTIVE SUPPORT)

The structure and the function of the pelvic floor is controlled by 4 muscular groups: (11,14).

- 1) **Pelvic wall:** Obturator + piriform (lateral wall). These muscles originate in the pelvic cavity and attach to the femur.
- 2) **Accessory:** Gluteus maximus + adductors (support structure) work synergy with levator ani.

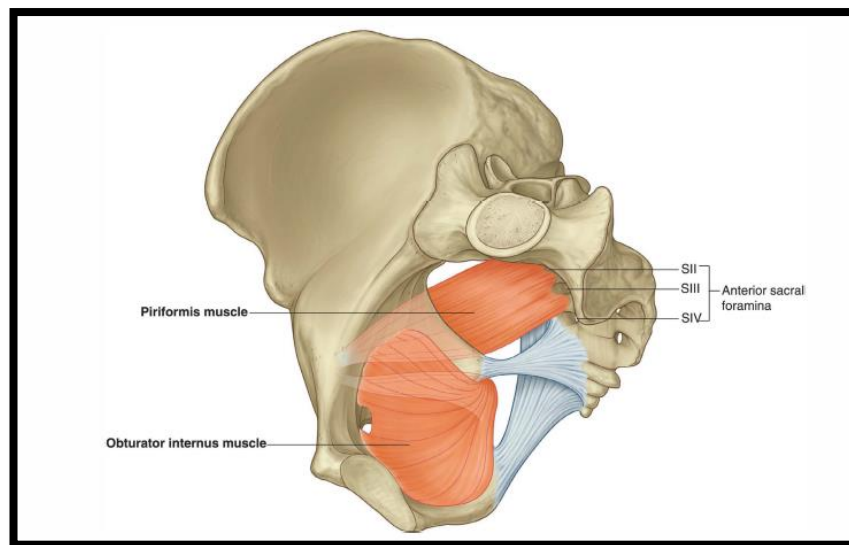


Figure 6. Pelvic wall muscles in charge of structural support (11).

### 3) Urogenital diaphragm:

- a. In the front: Ms. Bulbospongiosus + Ischiocavernosus + Superficial Transverse.
- b. Middle: perineal body or centre tendinous of perineum (from the vagina to the rectum).
- c. Back: Anal sphincter.
- d. It is also included the extern sphincter and the deep transversus of perineum, located between the two ischiopubic branches.

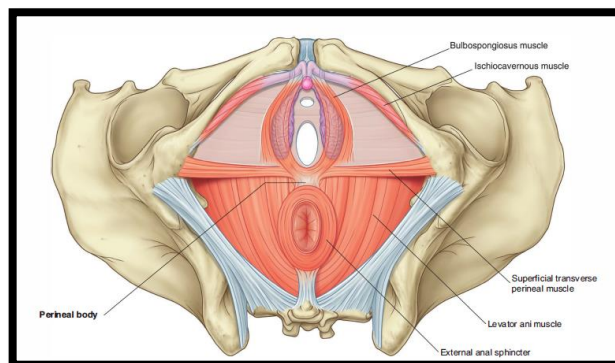


Figure 7. Urogenital diaphragm (11).

#### 4) Pelvic diaphragm:

It takes from the back of pubis until coccyx. It is concave from the top and convex from the bottom and inside it contains the pelvic organs. It is innervated by S2-S3-S4. Its 70% of fibers are type I and 30% type II.

a. Levator ani (Pubococcygeus + Iliococcygeus + Puborectalis). It is an important muscle for the support of the pelvic viscera and it maintains the closure of rectum and vagina. It is innervated by branches from the anterior ramus of S4 and by branches of the pudendal nerve (S2 to S4).

- Pubococcygeus: Originates at pubis and inserts at coccyx.
- Iliococcygeus: Originates at Internus Obturator and inserts at coccyx.
- Puborectalis: Originates at internal and lower side of pubis, and blend together posterior to the vagina and around the anal aperture.
- Posterior to the anal aperture, the muscles come together as a ligament called the anococcygeal ligament and attaches to the coccyx.

b. Coccygeus: It completes the posterior part of the pelvic diaphragm. It is attached to the tips of the ischial spines and to the lateral margins of the coccyx and sacrum. It is innervated by branches from the anterior rami of S3 and S4.

Both muscular layers explained (superficial and deep layer) are situated at different levels so they have different shape and orientation.

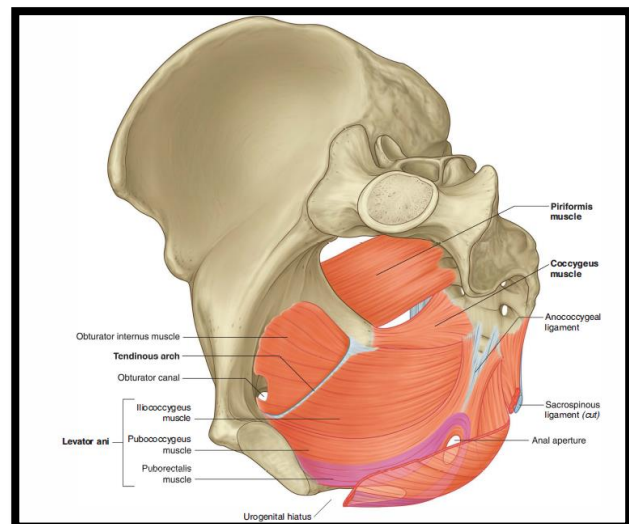


Figure 8. Pelvic diaphragm (11).



- 5) The perineal membrane: It is a thick, triangular fascial sheet, that fills the space between the arms of the pubic arch, and has a free posterior border. The perineal membrane is related above to a thin space called the deep perineal pouch (deep perineal space), which contains a layer of skeletal muscle and various neurovascular elements.

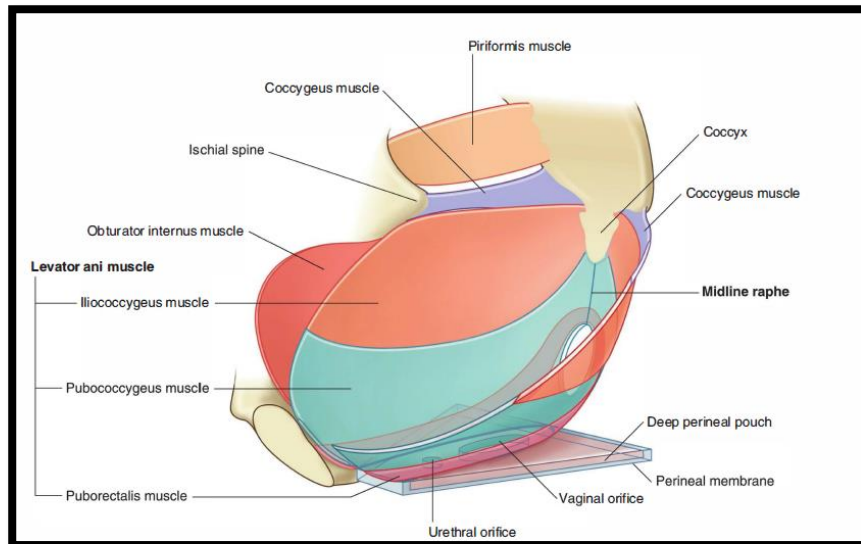


Figure 9. Perineal membrane (11).

## 1.2 URINARY INCONTINENCE

Urinary incontinence is defined by the ICS and the IUA as any non-voluntary loss of urine (1).

It is considered as a disease by the OMS since 1998, due to its repercussion in quality of life (QoL) and its psychosocial affectation (15).

The latest study in 2009 done by the National Incontinence Observatory (ONI) based on a systematic review (SR), concluded that around 6.000.000 people in Spain could suffer urinary incontinence. What surprises the most is the poor index of consultation because women take 3 years until they turn to the doctor. Nowadays, 80% of the patients who turn to any specialist improve or cure the pathology (16). However, the number is not exactly due to the shame people feel to face the pathology and how they try to hide it (2,15).

Furthermore, as it is mentioned above, there are a lot of studies published about prevalence for UI with a wide range. This is because of differences in the definition, in

epidemiologic methodology, and in demographic characteristics among the studies (4,15).

Worldwide it is estimated a prevalence of UI in women which vary in most studies between 24% to 45% (2,3). Talking about men, the literature about UI is still scarce. It is reported that UI occur twice as common in women as in men (4).

The consequences of UI are not only physical, it also includes social, sexual and psychological effects which produces a decrease on women's quality of life, who tend to diminish their activity and social participation (1).

#### 1.2.1 RISK FACTORS

The most important risk factors are pregnancy and vaginal delivery, although they become less important with increasing age (4). Age is one of the most well-known risk factors for pelvic floor dysfunction and the only which it is not modifiable and directly related to the incidence of stress urinary incontinence (SUI) and pelvic organ prolapse (17). Other risk factors reported in different studies are; diabetes mellitus, oral oestrogen, obesity, the use of forceps in a vaginal delivery, the amount of sport practice, respiratory disease and childhood enuresis (4,17,18).

### 1.3 TYPES OF URINARY INCONTINENCE

There are different types of UI classified according to the symptoms the women report, the signs observed by the clinicians and on the basis of urodynamic studies (3). The ICS defines generally 3 types of UI:

#### 1.3.1 STRESS URINARY INCONTINENCE (SUI)

It is defined as the involuntary urine leakage with physical exercise or doing some kind of exertion such as running, jumping, lifting, or with coughing or sneezing (3,5).

It is reported that SUI is the consequence of anatomical defects in bladder and urethra supporting structures or because of a dysfunction of the neuromuscular components that help control the urethral sphincter or urethral pressure. As a result, the urethra is not well closed during the exertion and this fact results in urine loss (3,5).

### 1.3.2 URGENCY URINARY INCONTINENCE (UII)

It is defined as involuntary leakage preceded by a sudden need to urinate. Women describe it as “sudden, compelling desire to pass urine which is difficult to defer”. This condition usually occurs due to a contraction of the detrusor muscle which increases bladder pressure. It is not clear what is the cause, often there is not any, but sometimes it is resulting from a neurological disorder (3,5).

It is frequent that women report other symptoms as frequency (urinate more often than usually) and nocturia (interrupted sleep because of the need to void) (5).

### 1.3.3 MIXED URINARY INCONTINENCE (MUI)

It is defined as the combination of both stress and urgency symptoms (3).

## 1.4 STRESS URINARY INCONTINENCE PHYSIOPATHOLOGY. ABDOMINO-PELVIC-DIAPHRAGM SYSTEM.

SUI is defined as the involuntary urine leakage associated with a physical effort. It is produced when vesical pressure overtakes urethral pressure. Actually, there are two accepted mechanisms which can cause SUI (19,20):

1. Intrinsic sphincter deficiency: Urethra lacks the capability to stay closed in repose, it keeps constantly opened.
2. Urethral hypermobility: Implies a weakening of the supporting structures of the pelvic floor (muscles, ligaments, nerves, connective tissue or a combination thereof). Urethra keeps its light closed during repose but during abdominal increasing pressures the urethra descends and urethral neck opens. As a consequence it causes the urine leakage. It is in these cases where the proper functioning of the abdomino-pelvic-diaphragmatic system, composed of the thoracic diaphragm, the abdominal wall and the pelvic floor, plays a fundamental role and where physiotherapy can act effectively.

In summary, there are three factors that directly affect in the development of urethral hypermobility and therefore in the SUI (19):

1. Hypertonia of the thoracic diaphragm: that increases the abdominal pressure.
2. Incompetent abdominal wall: that will direct the pressures towards the anterior area of the pelvic cavity which is the weakest zone.

3. Incompetence of the pelvic floor that allows an excessive visceral mobility.

1.4.1 FUNCTIONAL RELATION BETWEEN SYSTEMS: TRANSVERSALITY AND VERTICALITY

➤ **ABDOMINAL WALL (19):**

The abdominal hyper-pressure resulting due to an effort, generates a vertical force which falls on the perineum.

Transverse abdominal muscle acts as a point of support during the abdominal pressure generated because of the descending thoracic diaphragm during efforts as coughing, sneezing, catching weight, etc.

Pelvic floor in order to balance out this mechanic stress, generates a force towards anterior and above. The result of both forces, if there is a correct functional pelvic floor, is towards back and bottom, which is the strongest part of perineum (fibrous nucleus of the perineum, sacrum zone and coccyx).

However, if there is not a competent abdominal wall, the result of the force is towards anterior perineum, where there is the vagina and the bladder, causing more risk of suffering SUI because it is the weakness zone.

➤ **THORACIC DIAPHRAGM (19):**

There are many daily factors which increase the abdominal pressure. The thoracic diaphragm is the power unit of these increases. It descends during the inspiration and ascends during the exhalation. In an effort situation, it descends and pushes the viscera to the bottom. So for example, the cough of a person with a hypertonic thoracic diaphragm will increase more the pressure to the abdominal cavity than a person with a normal muscle tone.

➤ **SPRINGBOARD THEORY (20):**

According to this theory, the alterations of the tension applied by the muscles and ligaments on the fascia of the vaginal wall determine the opening or closing of the bladder neck and the urethra. To sum up, when all the factors are correctly working there is not SUI but when there are multiple factors badly working it can cause SUI.

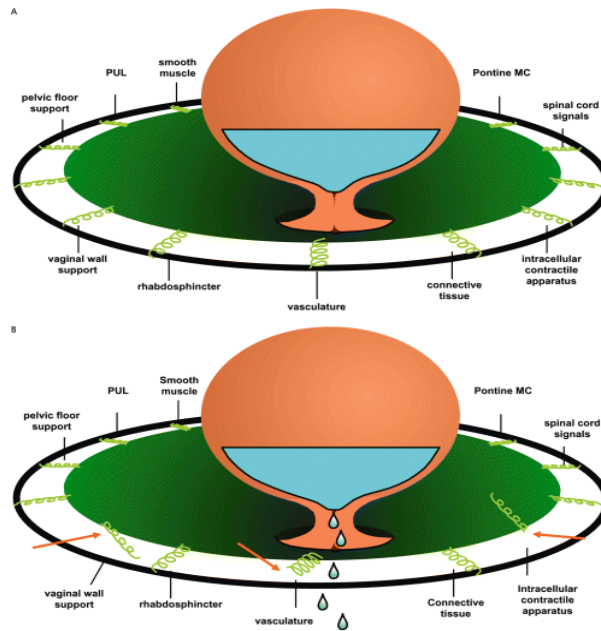


Figure 10. Springboard theory (11).

## 1.5 POPULATION

SUI appears when urethral pressure is insufficient or outpaced by vesical pressure during the moment of realizing a physical effort which produces an increase of abdominal pressure (21).

Repeated pressure actions alter in the short, mid or long term the passive fastening structures of the pelvic floor, occasioning urine leaks in detailed effort moments like running, jumping, laughing, coughing, sneezing and similar (22).

Among the activities which generate more intra-abdominal pressure (values higher than 30-50 mm Hg are considerate as hyper-pressure) stand out according to *Valancogne et al.* (23): a) abdominal exercises b) athletics c) basketball d) aerobic e) tennis. On the opposite side, swimming and cycling are those which less abdominal pressure generate (22,24).

So it seems clear that the prevalence of SUI in women elite athletes is very high and depends majority on the type of sport and the training frequency with also other risk factors (age, parts, corporal composition, etc.). The most common risk sport factors are: 1) training length 2) training frequency 3) number of years realizing sport 4) sport impact (22,25,26).

Different examples of studies in athletes are presented below:

*Eliasson et al.* (25) studied a group of female ex-trampolinists (n = 305) and found that 35% were affected in daily life, 53% reported to be psychologically affected, and 12 % stopped exercising because of UI, and what is more important, 76% keep suffering leakage also after having finalized their sport practice. The study also confirmed that 80% of springboard jumpers presented leaks of 28 g. This fact is really important because the middle age of these women was 16 years old.

An example of Spanish athletes, *Pérez et al.* (22) reported a SUI prevalence of 26,5%, while at the direct question only 5 recognised suffering SUI, so it emphasised the thesis that some women try to undervalue a grade of SUI.

Another study realized in two similar groups of women, with the only difference among them was the sport practice, demonstrated that 62,8 % of those who practiced sport suffered SUI during the sport practice and 60% during daily life. However, only 43 % of those who did not practice sport suffered SUI (27).

Nevertheless, the prevalence could change depending on the sport. This was demonstrated by a university athletes group. 144 women were questioned and 28 % confirmed leakage during the sport practice, the average age was 19'9 years and it was studied 9 different sports. Gymnasts (67%) were the most affected in compare with golfers (0%) (28).

## 1.6 DESCRIPTION OF THE INTERVENTION

### 1.6.1 PELVIC FLOOR MUSCLE TRAINING (PFMT)

Physical therapies to treat SUI include pelvic floor muscle training (PFMT) with or without biofeedback (BF), electrical stimulation, and weighted vagina cones (29).

Kegel was the first one introducing PFMT as an effective therapy for urinary incontinence in women. He published a successful study of 64 cases of female SUI where 84 % of his patients were cured, and that is why the treatment became widespread after the mid-1900s (3).

Although Kegel's studies weren't controlled and they lacked many outcome measures, several randomized controlled trials (RCT) and systematic reviews (SR) have confirmed that PFMT is effective for the treatment of SUI and MUI. Now, PFMT is recommended as first-line treatment (grade A). However, there are still doubts about

long-term outcomes. Cure and improvement rates in RCTs vary between 56% and 70%. Although there is strong belief in the evidence that PFMT improves, it does not abolish the condition. It is reported that 44-69 % women are cured, defined as < 1-2g of leakage on pad tests (26,29–31).

In contrast with other conservative treatments, PFMT seems to be more effective than electrical stimulation, oestrogen therapy, or the most common medication used as *Duloxetine* and *Oxibutina* in the treatment of SUI. It is concluded that electrically stimulated muscle contractions in humans are less effective than voluntary contractions for strengthening. The same is reported about vaginal cones (29).

The protocol published about PFMT follows recommendations for general training to increase strength of skeletal muscles (1,26,29):

Nº of repetitions: 8 to 12 repetitions close to maximum during 6-8 seconds in each position.

Rest period: 6 seconds.

Positions: Lied, biped, kneeled, and sited with legs apart.

Frequency: Intensive. Some studies report three times per day and others report three times per week.

Duration: The American College of Sports Medicine, based on strength training programs, recommends that it should last at least 15-20 weeks because they confirm that: *the first 8 weeks the changes are neural, followed by muscle hypertrophy due to increased volume and number of myofibrils*. In most studies the training program duration is 12 weeks because it already seems to reduce the urine leakage.

Bø (32) has summarised three concepts that might explain how PFMT may work:

1. Conscious PFM pre-contraction during physical stress:

“The Knack” is defined as the pre-contraction of pelvic floor muscles (PFMs) just before physical stress in order to prevent urinary leakage. The patient has to contract PFMs before the increase of intra-abdominal pressure and try to hold this contraction during the physical stress.

2. PFM strength training:

The purpose is to rise the position of the levator muscle plate in the pelvis in order to facilitate the automatic PFM's response to face intra-abdominal pressure changes.

3. Facilitation of PFM contraction through abdominal muscle contraction:

It is reported that the contraction of transversus abdominus is accompanied by a co-contraction of PFM's. But the role of this abdominal muscle is still unclear to treat female urinary incontinence.

### 1.6.2 BIOFEEDBACK

Many women are not aware of how identifying, controlling and coordinating pelvic floor muscles or how to avoid a rise in intra-abdominal pressure, so they don't know how to perform PFMT. Biofeedback is a therapy which relays visual and/or auditory evidence of pelvic floor muscle tone using a surface electrode inserted into the vagina (33). Its relevance lies in the intention to teach subjects to "*bring certain physiologic processes under voluntary control*" (34).

Biofeedback by itself is not a treatment for UI but as an adjunct to PFMT provides feedback signals on what muscles are contracting, which provides the patient a better identification of the correct muscle group training and at the same time increases patient's motivation, so an improvement in self-control of incontinence might result of it (34–36).

Hsu *et al.* (35) carried out a meta-analysis which studied the effects of biofeedback assisted pelvic floor muscle training in patients with urinary incontinence after radical prostatectomy in comparison with pelvic floor muscle training alone. Authors literally concluded that:

"Biofeedback-assisted pelvic floor muscle training exerts immediate-, intermediate-, and long-term beneficial effects on urinary incontinence compared with pelvic floor muscle training alone when urinary incontinence was measured objectively."

Pelvic floor muscle exercises are applied either alone (home program or clinic/supervised programs) or with BF especially in routine clinical practice and in the literature. Furthermore, the EAU defines in its *Guidelines of Urinary Incontinence*, a



Recommendation level “A” the use of BF as an adjunct in women with SUI (*annex 12.10*) (36,37).

### 1.6.3 IMMERSIVE VIRTUAL REALITY

Immersive Virtual Reality (IVR) is a computer technology with artificial sensory feedback which provides individual experience activities similar to real-like events. The special defining features are “interaction”, referred to the presence of different sensory channels (sight, hearing touch, and even smell) and “immersion”, referred to involvement of the participant with the virtual environment (38,39).

It has a high degree of ecological validity (the extent to which an experiment reflects the real world), and this increases the probability that the acquired skills transfer to the real world. Indeed, it offers many advantages to the therapist. The therapist can observe realistic perceptions, reactions and emotions in the patient in a real-like three dimensional environment (38,39).

Immersive virtual reality rehabilitation (IVRR) has three key elements that are important in motor learning (38):

- Repetition.
- Sensory feedback.
- Motivation of the subject.

Virtual reality has previously been used in some training settings, such as flight simulation training for pilots and procedural training for surgeons. Talking about health care, so far IVR is being used to treat phobias, post-traumatic stress disorders, and body image disorders. A SR on the treatment of stroke vascular brain, concludes that the treatment only with virtual reality does not show significant results on the functional improvement of upper limb compared to conservative treatment, but classifies the level of evidence of the studies as low quality and highlights the need to conduct more studies of better quality for the use of IVR in the field of rehabilitation (40).

*Botelho et al.* (33) designed a virtual reality intervention protocol conducted on nulliparous women without urinary symptoms and postmenopausal women with mixed urinary symptoms. The study concludes that “*virtual reality program promoted an increase in pelvic floor muscles contractility and a decrease in postmenopausal urinary symptoms*” but it lacks of high methodology.

*Elliot et al.* (34) already did the quasi-experimental pre-test, post-test pilot study to evaluate “the feasibility of using a PFMT/VRR program to treat MUI in older woman, to evaluate its effectiveness on symptoms and quality of life and to gather quantitative information regarding patient satisfaction with the PFMT/VRR training program”. Results are not published yet.

On the other hand, an article published in 2017 by the International Urogynecology Journal, reported that (41):

“European urogynecologist and physical therapists welcome innovative treatment options for the conservative treatment of SUI such as portable wireless biofeedback and serious gaming. Scientific evidence is considered a prerequisite to incorporate such innovations into clinical practice.”

Besides, a meta-analysis from 2017 on neurorehabilitation concluded that some specific games are more effective in improving motor upper limb and movement/balance functions compared to conventional rehabilitation (42).

However, some authors declare in their studies that there is insufficient evidence to reach conclusions about the effect of IVR on other functions, which are the most significant characteristics of IVR and that there is not enough knowledge about effects in the longer term (39).

Otherwise, it is reported that any training program diminish with time if PFMs have not reached an automatic level. It is shown that there is between 5-10% loss of muscle strength per week after training cessation. Additionally, some women may find the exercise hard to conduct on a regular basis. It is considered that to maintain strength gains or slow strength loss, the intensity should be maintained but the volume and the frequency can be reduced, so IVR could be a help tool to keep patient’s motivation and avoid training cessation (30).

## 2 JUSTIFICATION

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Involuntary urine loss has been reported to occur in about 5-69% of women. Recent studies conducted by the ONI report the high prevalence of people suffering from urinary incontinence in this country (2,4).

In regard to the treatment, many systematic reviews and the European Association of Urology evidences PFMT as the first-line treatment (grade A) (3,4).

However, it should not be forgotten that one of the principal derivate problem of this pathology is the high economic spending in sanitary towels and containers (6,43).

Many studies carried out, evidenced the high prevalence of SUI in elite women athletes. Urinary incontinence is a socially embarrassing condition, not only causing withdrawal from social situations and a decrease in quality of life but also may lead to withdrawal from regular physical and fitness activities (29).

So far, there is no agreement on the most appropriate exercise protocol, so it seems significant to do more research about it. Moreover, no RCTs have yet been conducted on the effect of PFMT on elite adult women athletes with SUI, since it is assumed that elite athletes would respond to the treatment in the same way as other women do. However, given the non-stop impact on their pelvic floor, they may need stronger PFMs than non-adult athletes (26,29).

In addition, the use of IVR is increasingly wider in the field of rehabilitation, which is important to assess the effectiveness of this new technology for future designs and uses. It can also be a work tool that allows to maintain and / or increase the frequency of treatment without the need to attend the rehabilitation centre (40). The protocol presented in this study, up to the knowledge of the author, will be the first RCT on the use of this new technology in the field of urinary incontinence.

The aim of this study is to evaluate, for the first time, the effectiveness of PFMT in female elite adult athletes with SUI using an immersive virtual reality program in order to reduce the urine leakage and improve the quality of life of these population.

### 3 HYPOTHESIS

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Stress urinary incontinence treatment in elite female adult athletes using a program which combines PFMT and BF with IVR is more effective in improving quality of life than the conservative PFMT treatment with biofeedback alone.

### 4 OBJECTIVES

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#### 4.1 PRIMARY OBJECTIVE

To evaluate the effectiveness of PFMT using immersive virtual reality for stress urinary incontinence based on quality of life in adult women elite athletes compared to normal care.

#### 4.2 SECONDARY OBJECTIVES

To assess the effect of PFMT using immersive virtual reality for stress urinary incontinence compared to normal care on:

- Urine leakage
- Incontinence severity
- Muscular strength of the pelvic floor
- Treatment adherence

## 5 METHODOLOGY

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### 5.1 DESIGN

The study is a randomized controlled double blind trial. It is a pre-post study with follow-up at three, six and twelve months. It follows the Checklist SPIRIT 2013 (44).

The aim of the study is to evaluate the effectiveness of a health intervention based on the idea of secondary prevention, since it is applied to patients with a base pathology, in this case, female adult elite athletes with SUI.

The present study divides the sample into two groups; a Control group and an Experimental group. The first group (control group) will follow a conservative protocol of PFMT with biofeedback using a game application. It will be named as “Group 1”.

The second group (experimental group) will follow the same protocol of PFMT with biofeedback through an immersive virtual reality program using the same game application. It will be named as “Group 2”.

The volunteers women athletes, recruited from *Sant Cugat CAR*, who comply the inclusion criteria will be given a link of the web platform “*Open Clinica (annex 12.1)*” (45) to sign in, in order to participate in the study. The distribution of the patients to the groups will be randomized by the same online platform “*Open Clinica*”. Each patient will introduce her social security number to the program and automatically they will be classified in Group 1 or Group 2. The randomization of the trial will be done to avoid selection bias in order to realize a valid statistical analysis and to guarantee that the randomization allows creating two groups with similar and comparable characteristics thus all the participants will have the same possibilities to receive an intervention or the other.

Once they have been signed in, *Open Clinica* will inform the patient when and where will be the treatment. Group 1 will be treated in a sport facility from *Sant Cugat CAR* (separated with room dividers) and Group 2 will be treated in another sport facility from the same place. The results of the randomization will be registered in *Open Clinica* folders, only accessible by the computer technician, without specifying if they are Control group or Experimental group.

Participants will be blinded because they won't know in which group they are, the experimental or the control group. The physiotherapists who will treat the patients will be external from the intervention, and they won't know which is the control group and which is the experimental group, but they will know which therapy they have to carry out.

The patients' follow-up will be done through various assessments. The first assessment will be at the beginning of the study (enrolment) for all participants in order to confirm the inclusion criteria. The variables will be assessed, both from the experimental group and for the control group, firstly on Monday, September 3, 2018. Next assessments will be after three months (QoL, urine leakage, incontinence severity, and PFMs strength), six months (treatment adherence) and twelve months (all the variables).

During the first two weeks, participants will carry out the intervention with the presence of the physiotherapist. Afterwards, the patients will continue with the treatment without him/her. It will be patients' responsibility to attend the place and at the time of treatment during the following 12 months of the study.

## 5.2 STUDY SUBJECTS

In this study the target population will be the adult elite women with SUI from a High Performance Center, specifically from the *Sant Cugat CAR*.

According to the Spain Sports Council, it is defined as an elite athlete those who have been accredited as such, by resolution of the President of the Sports Council. The characteristics of high level athletes are published in the BOE "*Real Decreto 971/2007, de 13 de julio, sobre deportistas de alto nivel y alto rendimiento*" (46).

It is important to highlight that before doing the study, the author has contacted via email with the physiotherapist in charge at the *Car Sant Cugat, Marta Bou*, and she reported that unfortunately many sportswomen from the *Sant Cugat CAR* suffer from this condition but few talk about it, so the physiotherapist stressed that it is a pathology which is hardly treated but it should be.

To ensure that both groups (control and experimental) are heterogeneous and that the results are not due to the homogeneity, sociodemographic characteristics will be collected at the baseline (*annex 12.2*) (47,48).

For the estimation of the sample size, the *Calculus Mostral Granmo* (49) will be used, which will carry out the calculation of the sample by contrast of hypotheses and through the comparison of two independent means. The sample size calculation is based on the study of Sjöström et al. (47). It is assumed that a reduction of 2.52 points in the International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF) will be sufficient to be considered clinically relevant (50).

Accepting an alpha risk of 0.05 and a beta risk of 0.2 (statistical power of 80%), using a two-sided test, and assuming 15% withdrawal rate, it will be necessary to include 32 subjects in each group to detect a difference greater than 2.52 units (assuming a baseline distribution of 3.3 (47)).

As mentioned before, an external computer technician will be the responsible to keep the assignments using *Open Clinica*, on a computer assigned to this study that is inaccessible to the rest of the study staff.

### **5.2.1 INCLUSION CRITERIA**

- Urodynamic SUI (urethral closure pressure equal to or greater than 20 cm of water)
- ICIQ-SF questionnaire > 0
- Adult elite woman athlete
- Nulliparous
- Signed Informed Consent

### **5.2.2 EXCLUSION CRITERIA**

- Detrusor over activity
- Neurological diseases (such as multiple sclerosis, involvement of some nerve...)
- Muscular diseases (such as infections, inflammations...)
- Anomaly genital bleeding
- Pelvic organ prolapse (urethrocele, cistocele, rectocele, enterocele, uterine prolapse, vaginal dome prolapse, rectal prolapse)
- Active genital infections

In addition, few women who report UI symptoms (and/or prolapse) are as well affected by another serious condition. Because of that, the National Institute for Health and Care Excellence (NICE) created a *Guidelines for Investigation of Urinary Incontinence* in order to identify red flags and immediately refer to a specialist (51,52).

For UI, indications for urgent referral are (51,52):

- microscopic haematuria in women aged over 50 years
- visible haematuria
- recurrent or persisting urinary tract infection associated with haematuria in women aged 40 years or over
- suspected malignant pelvic mass

Besides, NICE guidelines indicate that referral should be considered in cases of (51,52):

- Persisting bladder or urethral pain
- Clinically benign pelvic masses
- Associated faecal incontinence
- Suspected neurological disease
- Symptoms of voiding difficulty
- Suspected urogenital fistulae
- Previous continence surgery
- Previous pelvic cancer surgery
- Previous pelvic radiation therapy

All the symptoms and / or pathologies mentioned in the previous paragraphs, will be considered as exclusion criteria.

In order to ensure that the patient meets the inclusion criteria and does not present any exclusion criteria, the physiotherapist responsible to carry out the treatment and a urogynecologist, will perform the first day (the same day participants sign the informed consent) an urogynecological anamnesis (*annex 12.3*).

If during the trial any physiotherapist, notices any of these symptoms mentioned before, the treatment must stop and the patient is excluded from the study. A table of recommendations summary is shown at the annex (*annex 12.4*) (51).



At the time the subjects meet these criteria, they will receive a fact sheet (*annex 12.5*) and will sign the informed consent (*annex 12.6*), based on the Declaration of Helsinki (53), where the study and its purposes are explained in addition to the approval of the study by an Ethical Committee.

### 5.3 STUDY VARIABLES

#### 5.3.1 TYPES OF OUTCOME MEASURES

##### ✓ **International Consultation on Incontinence Questionnaire-Short Form**

The Second International Consultation on Incontinence, settled up a new questionnaire that identifies people with urinary incontinence and the impact on the quality of life (QoL): the International Consultation on Incontinence Questionnaire (ICIQ). Besides, it was developed one short version of this questionnaire with the objective to be used both in research studies and in the clinical practice: ICIQ short form. Its final version, which has been translated and culturally adapted in various countries, consists of 3 items («frequency», «quantity »and« affectation »), plus a group of 8 questions related to the type of UI with only the purpose to describe and guide on the type of UI (54).

ICIQ-SF is the first questionnaire designed for diagnosing UI validated in Spain.

“The psychometric properties of the ICIQ-SF are satisfactory and allow to recommend the use of the questionnaire in the clinical practice” (54).

The total score of the sum of the first 3 items, goes from 0 to 21 points (*annex 12.7*). It is considered UI diagnosis any punctuation > 0 (54).

It is established that the minimal important difference to consider clinically relevant improvements post-treatment in women with SUI is 2.52 (50).

##### ✓ **Pad test**

The ICS proposes the use of the called "Pad Test" or "Test of the Compress" to measure urine leakage (55,56).

This test is carried out over an hour, with the bladder full and after ingesting a volume of 500 cl of water in a maximum period of 15 minutes (55).

At half an hour, the patient must perform the following activities: climb a floor of stairs, get up and sit down ten consecutive times, cough ten times, run on the same spot for

a minute, bend over to take an object from the ground five consecutive times, and finally wash hands in cold water during a minute (*annex 12.8*) (55).

The compress is weighed in a digital scale before and after the exercises to quantify the urine leakage. Weight differences of + 1 or + 2 g are considered normal since they can be due to the sweating itself of the perineum or to vaginal discharge. An increase of 2 to 10 g are considered mild incontinence, 11 to 50 g represents moderate incontinence and > 50 g means severe incontinence. In this study, results post-treatment of 1 g or less will be noted as cured, while 50% or more decrease in wet weight will be considered as improvement (55–57). In a study performed by *Sutherst et al.* (55) in a population of 100 and 50 continent women, the average loss of urine following the Pad Test was 0.8 g in patients with normal control of the urine, 25.7 g in women with stress urinary incontinence and 20.7 g in patients with urgency urinary incontinence; they also observed that while the patients with stress incontinence suffered an average of 5-6 leaks during the duration of the test, women with urinary urgency only referred 1-2 urine losses (55).

Although it is published that in long-term Pad Tests (more than an hour test) the correlation between the test and the severity of incontinence is better, a number of variables can affect its validity (hormonal status, environmental conditions, physical activity level and the type of pads used). Furthermore, the short-term shows a good correlation with a self-assessment questionnaire (55) .

#### ✓ **Incontinence severity index (ISI)**

“It consists of two questions regarding frequency and amount of leakage. It categorizes urinary incontinence into moderate, severe, and very severe” (58).

The validity of the questionnaire is equally demonstrated in primary and hospital care (*annex 12.9*) (58).

#### ✓ **Perineometry**

*Laycock* developed and validated a valuation palpation protocol called PERFECT (P= power, E=endurance, R= repetitions, F= fast, ECT = every contraction timed) to evaluate the strength of pelvic floor muscles. The present study will use the Modified Oxford Scale or Laycock Scale to measure strength (55,59,60) .

- Power: Measured on a modified Oxford scale during a maximal voluntary contraction (MVC).
- Endurance: Expressed as the length of time, up to 10 seconds, that a MVC can be sustained until a detected strength loss of 35-50%. A simultaneous contraction of hip adductors and glutei and the stronger co-contraction of transversus abdominis could indicate the fatigue of PFMs. Breathe-holding should be avoided so if it is detected the physiotherapist should instruct to contract the pelvic floor on expiration.
- Repetitions: Number of repetitions, up to 10, of MVC with a rest time between contraction and contraction of 4-6 seconds. On the practice, once the patient is able to contract 10 repetitions of 10 seconds MVC, the rest time could be reduced.
- Fast: Number of fast contractions of one second until the muscle fatigues, with a maximum of ten (after a short rest at least one minute). The patient will be instructed to “contract-relax” as quickly and strongly as possible.
- Every Contraction Timed: Reminds the examiner to time and record the above sequence of events so that the exercise program of each patient is performed in an individualized and specific way.

During the assessment of pelvic floor muscles contraction, the physiotherapist should pay special attention to the presence or not of parasitic contractions, mainly of the abdominal muscles, adductors and buttocks. If the physiotherapist detects these synergies during muscles assessment, he/she must place the hand on the abdomen of the patient, in order to feel any muscular contraction of this region, at the same time that he/she can observe possible contractions at the level of thighs and buttocks (55).

However, the perineometer is the most used objective test in all the analysed studies (56,61). As in the palpation evaluation, in perineometry can also be applied the PERFECT protocol in instrumental assessment, with the advantage that it can be done not only in the gynaecological position, but also in sitting and standing (55).

GRADE	MUSCULAR RESPONSE	DEFINITION
0	Nothing	No discernible muscle contraction
1	Flicker	Trembling movements of the musculature (<2" contraction)
2	Weak	Weak pressure without flicker but without any discernible lift ( $\geq 3$ " contraction)
3	Moderate	Increased pressure and slight elevation of the posterior vaginal wall (4-6" x 3 times)
4	Good	The examiner's fingers are tight firmly; lifting the back wall of the vagina against moderate resistance (7-9" x 4/5 times)
5	Strong	Holding with fingers strength and lifting of the back wall against a maximum resistance; the examining finger is squeezed and drawn into the vagina ( $\geq 10$ " x 4/5 times)

Table 2: Modified Oxford rating scale for the pelvic floor musculature; Laycock (55,59,60).

PERINEOMETER (MM HG)	LAYCOCK VALUATION SCALE (GRADE)
0-30	1-2
30-40	3-4
50-60	5
>60	5+

Table 3. Approximate equivalences between the scale of Laycock assessment and the pressure measured by the perineometer in mm Hg (55).

### ✓ Treatment Adherence

Adherence is defined by the IUA and the ICS as (62):

*"The extent to which a client/patient's behaviour corresponds to the agreed treatment protocol and/or regime as recommended by their healthcare provider. It does not refer to the intervention itself; rather, the patient's commitment to undertaking the behavioural change to adhere to the intervention"*

To measure treatment adherence it will be taken into account the times the participant access to the game application and carry out the exercises established. Each time the patient accesses the application, it is registered with a patient number and the date.

## 5.4 DATA COLLECTION AND ANALYSIS

The data collection will be done through the electronic platform *Open Clinica* and will be based on a Good Clinical Practice Standards Course (BPC) published on May 17th, 2011 by the Central Unit of Clinical Research and Clinical Trials of the University Hospital of Vall d'Hebron" (45,63). The *Open Clinica* data base will contain the variables: QoL punctuation measured with ICIQ-UI SF test, grams of urine leakage measured with Pad Test, incontinence severity measured with ISI test, pelvic floor muscle strength measured with perineometry and treatment adherence measured by the times the patient access to the game application. Those responsible for collecting the results of the measures will be physiotherapists external from the study.

The data collection will basically contain a sheet with personal data of the patient, the anamnesis and an assessment of the variables to be studied with the corresponding measurement tools previously explained. The information (personal data and anamnesis and the specific tests) will be collected before starting the study, both from the experimental group and from the control group, and then at three, six and twelve months, as it has previously been explained on the design.

These data will be stored without risk of disclosure in accordance with the privacy and data protection of patient's law and the Catalonia physiotherapy deontological code (64).

## 5.5 GENERALIZATION AND APPLICABILITY

In the event the results of the study conclude that the treatment by pelvic floor muscle exercises combined with BF using immersive virtual reality on elite adult women athletes, is more effective than conservative treatment with PFMT with BF alone, infer could be done using the presented protocol treatment to patients who stop the treatment due to boredom or lack of motivation. The present study is carried out in a specific population, adult women elite athletes, since it is a type of population highly susceptible to suffer the pathology. In addition, until now there are no RCTs with a good methodological quality on PFMT treatment for SUI in this type of population. To make a generalization of the results and justify their applicability within the health sciences, a larger sample of patients would be needed. More financial resources would

also be needed to provide patients with their own virtual glasses and a BF so that they could perform the treatment from their home.

Although the selected population is very specific in terms of the amount of sport they perform, it would be possible to extrapolate the results to women in adulthood who suffer from stress urinary incontinence without taking into account the sport practice. Likewise, it would be a new bibliographical contribution for physiotherapy, although other studies are needed to confirm the hypothesis through replicas of it.

Generally, the current scientific culture assumes that negative results are not worthy of attention. However, *Matosin et al.* (65) present another perspective about this fact. They assume that scientists' duty is: publish all data because negative findings are still important findings and have a hypothesis to explain the finding.

*"Only then can we work towards an improved scientific paradigm" (65).*

To sum up, in the case of obtaining contradictory results to the exposed hypothesis, it would also be useful, since it could confirm that the use of this expensive therapy would not be significantly effective in SUI treatment in respect to the treatment currently used in the centres of health. In this way, the conclusion would be that more studies of alternative therapies are needed for those patients, previously commented, who have difficulty to follow the treatment without ceasing it.

## 5.6 STATISTICAL ANALYSIS

All the data obtained during the study collected in *Open Clinica* will be exported to the statistical program SPSS (Statistical Package for the Social Sciences) in order to perform the analysis of all the variables in the study. The univariate and bivariate descriptive analysis will be applied in the first place. For the univariate analysis, frequency tables will be made. Quantitative variables will be described using measures of central tendency (mode, arithmetic mean and median), measures of position (quartiles and percentiles), measures of dispersion (amplitude, range interquartile, variance, standard deviation), and measures of shape (normal distribution, asymmetry, pointing) (66).

To facilitate the reading of the results, it will be used different graphical representations, such as the histogram and frequency polygon for the quantitative ones or the bar

diagram for the qualitative ones. In the bivariate analysis, it will be used the contingency tables and the comparison of frequencies using the Pearson Chi-square test (qualitative), the dispersion diagram and Pearson's linear correlation coefficient (quantitative), comparison of the means (T-Student, qualitative-quantitative). Once the descriptive part is done, it is needed to know the evidence provided by the data *for or against* the proposed hypothesis. For this, it will be used the test of statistical significance or hypothesis contrast in order to reject the null hypothesis ( $H_0$ ), to accept the alternative ( $H_1$ ) (66).

$H_0$  = Stress urinary incontinence treatment in elite female adult athletes using a program which combines PFMT and BF with IVR is not more effective in improving quality of life than the conservative PFMT treatment with BF alone.

$H_1$  = Stress urinary incontinence treatment in elite female adult athletes using a program which combines PFMT and BF with IVR is more effective in improving quality of life than the conservative PFMT treatment with BF alone.

The differences between the groups will be contrasted using Student's-test or the Mann-Whitney test when assuming a non-normal distribution. Regarding statistical inference, it will be assumed a 95% confidence interval, with an  $\alpha$  value of 0.05, that is, a 5% error  $\alpha$  (66).

A group appointed by the study sponsor will carry out the statistical analysis. It will include at least one specialist in biostatistics and methodology independent of the research.

The results will be analysed before the treatment, after 12 weeks, 6 months, and 12 months.

## 5.7 INTERVENTION PLAN

The intervention is based on an European project called “WOMEN-UP” developed by a consortium composed of eight partners from six EU countries. According to the responsible:

“The main objective of the WOMEN-UP project is to improve the quality of life of urinary incontinence patients through a holistic and cost-effective ICT-solution for a conservative home treatment, allowing for the self-management of the chronic UI disease via a decision support system and a secure remote medical supervision” (67).

The aim of the present RCT is to create a treatment protocol based on *WOMEN-UP* with the addition of IVR specifically to be applied to elite women athletes, with the possibility of extrapolating it to any woman with SUI. The computer technician of the study will design a game application that can be used in a computer, mobile, tablet, etc. Both the control and experimental groups will use the application to carry out the treatment. The application will include different exercise programs that could be designed individually for each patient depending on the results of the first assessment in the PERFECT protocol. The specificity is given by the IVR game.

The IVR will provide individual experience activity based on real-like sport. Every women (experimental group) will have the possibility to strengthen her pelvic floor muscles in an “immersion” of her competition sport with the objective that the acquired skills transfer to the real world. As Bø (32) reported, in order to reach an automatic pre-contraction during specific physical stress before the increase of intra-abdominal pressure. The application designed name will be “TRAIN-TO-PLAY” (TTP).

### 5.7.1 SYSTEM CHARACTERISTICS

The project consists on creating an application with *pelvic floor muscle rehabilitation games* using immersive virtual reality glasses. It will include an intravaginal device that can be connected wirelessly or via Bluetooth to a computer / television / tablet /mobile phone, etc.

The device should work with the biofeedback, that is, the biofeedback is a technique used to control the physiological functions of the human organism, through the use of a feedback system that informs the subject of the state of the function that is want to control voluntarily.



### Device summary:

- ✓ Intravaginal device with connection wirelessly or via Bluetooth to a computer / TV / tablet / mobile phone, etc. as well as immersive virtual reality glasses.
- ✓ The device works as a clinical biofeedback.
- ✓ The device transmits the information received, based on PERFECT protocol, to the *TTP* app that is connected monitoring through a graphic interface.
- ✓ The challenge of the Immersive Virtual Reality sport is a specific rehabilitation program established by the physiotherapist based on patient's needs.
- ✓ The physiotherapist is able to customize the challenge game.
- ✓ The IVR program could include advice from the physiotherapist.
- ✓ The *TTP* app record each patient's training.
- ✓ The app allows the patient to follow up the training at home and the therapist can access the app to observe rehabilitation progress without the need for the patient to assist consult.
- ✓ It is a way to continue with the long-term treatment because the appointment with the physiotherapist is not necessary since through the app they can be in contact.
- ✓ The app and the device allows the patient to choose whether she wants to train with IVR or whether she wants to train without IVR.

Currently, already exists an immersive virtual reality rehabilitation system with biofeedback called "*VAST.REHAB*" classified as a medical device, and it received CE marking conforming to the regulatory system of the EU's medical device directives. Although the system allows its use in many conditions (cerebral vascular accidents, multiple sclerosis, cerebral palsy, parkinson's disease and extrapyramidal syndromes, brain tumours operations, spinal cord injury, traumatic brain injury, muscular atrophy, muscle weakness due to lack of mobility, endoprosthesis, stable fractures, limb amputations and balance and equilibrium disturbances) it does not include the possibility to treat urinary incontinence condition (68). So the idea of *TTP app* is to create an app based on "*VAS.REHAB*" characteristics but designed for UI treatment.

#### 5.7.2 SYSTEM ARCHITECTURE

The architecture of the device is already developed in a final master assignment of the "*Universitat Politècnica de Catalunya*" but it has not been tried out yet, so it will try to

contact with the author and the tutor of the work to use the project of the device including the new characteristics of immersive virtual reality (16).

The following diagram shows the general structure of the proposed system:

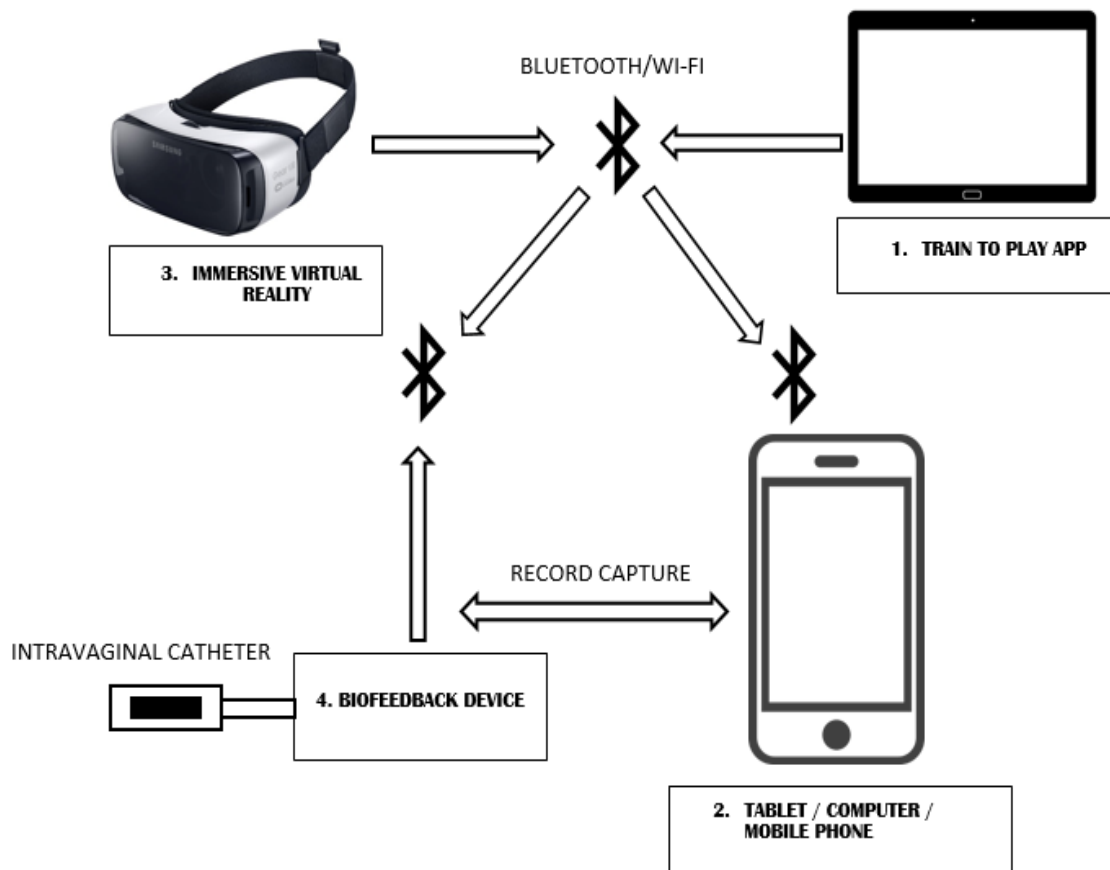


Figure 11. Diagram of the project architecture.

### 5.7.3 FIRST ASSESSMENT

Both groups will receive a first appointment which will consist on:

1. Patient education: Make the patient understand her condition in order to empower her to play an active role in her treatment.
2. Learning the contraction: Teach how they should perform pelvic floor muscle training.
3. Physical exploration by the physiotherapist
4. Establish the treatment

### **1. PATIENT EDUCATION:**

It is important to explain the patient the importance of her condition in order to make her active to the treatment. Having passed two weeks of the treatment, the patient will have to continue with the PFMT by her own so it is important to show the relevance of SUI (62).

### **2. LEARNING THE CONTRACTION:**

First of all, the physiotherapist will do a digital palpation to explain the patient how to contract PFMs. The patient is positioned supine on a stretcher with knees flexed and abducted hips. Next, the professional will place the index or the index and the middle finger, within 4-6 cm of the vaginal introits and teach the patient how to do the contraction avoiding abdominal contraction (61).

During the first two weeks participants will carry out the treatment with the presence of the physiotherapist in order to make sure that the contraction is done correctly.

To make sure that all the physiotherapists teach the same way, they will have a standard guide with some expression tools (69):

- “Lift the pelvic floor up from the surface by pulling up and contracting around the urethra, vagina and rectum. Squeeze so hard that you feel a slight trembling in your vagina. When you squeeze hard enough, you can feel the lower part of the stomach being pulled in slightly at the same time. Try to feel the difference between relaxing and tightening the pelvic floor”.
- “Try to stop the flow when you are urinating. If these muscles are weak, it may be difficult to stop the flow when it is strongest. Do not use urination for training, as this can interfere with the ability to empty your bladder completely”.

### **3. PHYSICAL EXPLORATION (55):**

#### **a. Visual exploration:**

- i. State of skin: The presence or not of abrasions, erythema, mycosis, vesicles or leucorrhoea that could indicate an infection, in whose case the treatment will be suspended immediately and it will be referred to the gynaecologist.
- ii. Colour: Gives an idea of vulvovaginal trophicity, main sign of the oestrogen level. In the case that it is detected a very pale coloration

of the mucosa, with a pearly colour and a loss of elasticity in the labia minora it is convenient to derivate the patient to the gynaecologist to assess the need of an estrogenic treatment, since the level of hormones can greatly influence the ability of contraction of the perineal musculature and in the success of the physiotherapy treatment.

- iii. Opening vagina diameter and ano-vulvar distance: Under normal conditions, the introit vaginal is closed in the resting state, except of multiparous women presenting a slight opening. It is considered a normal opening when the diameter of the vaginal introit does not exceed 25 mm. Distance ano-vulvar measures the length of the tendinous centre of the perineum, insertion point of the perineal musculature, whose normal length is between 2.5 and 3.5 cm.
- b. Palpation: The palpatoria exploration brings to the physiotherapist a great relevance information about the state of the muscles and joints of the pelvis, as well as the static of the organs of the pelvis. By palpation could be assessed the tone of the perineal muscles, posterior and anterior walls of the vagina, the urethra, and the degree of mobility of the coccyx.

Remember that before beginning the treatment the physiotherapist has already carried out an urogynecological anamnesis. As previously mentioned (*section 5.2.2*), the presence of any of the symptoms considered as red flags will immediately force to stop the study and refer the patient to a specialist.

#### **4. ESTABLISH THE TREATMENT:**

The first assessment to establish the treatment will be done by a perineometer. Perineometry is defined as “*measure of strength generated via change in pressure within a balloon connected to a pressure sensor*” (61).

In SUI the urine leakage is correlated with pelvic floor muscle strength, so the treatment will be based on the strength parameter. According to a metha-analysis, measuring strength by digital palpation using the Muscle Strength Oxford Scale must be considered subjective due to differences among technicians' interpretation (8), that is

why it is decided to measure the strength by perineometry. However, there is no current “gold standard” to quantify PFM strength in females with UI (61).

In the present study, it will be used the trademark *Peritron* of LABORIE Medical Technologies Canada. It disposes of three different sensors but the author will only use the vaginal sensor. In order to ensure that all professionals use the instrument correctly, they will be dispensed the manual *Peritron Owner's Manual V07 PERI-UM01* where it is detailed how to make a good use of *Peritron*.

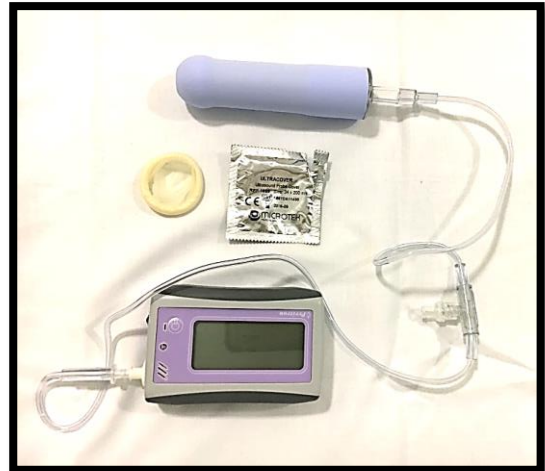


Figure 12. Peritron device

There is no standard protocol for the treatment of pelvic floor exercises because it is an individualized treatment based on the results of the first assessment. The literature indicates a lack of standardisation and so it is studied that a uniform, standard regimen is not appropriate. Instead, it is proposed to progress sequentially as *power* and *endurance* increase. It is established that 8-12 repetitions close to maximum during 6-8 seconds with 6 rest seconds, is considered a quiet good contraction (1,60,70).

It is relevant to highlight that the physiotherapists responsible for teaching the treatment (P1) and the physiotherapist responsible for evaluating the variables (P2) will be qualified and specialized in pelvic floor treatment. P1 will be responsible for establishing the treatment needed in each patient.

The treatment will be the following:

✓ **CONTROL GROUP:**

- Pelvic Floor Muscle Training + biofeedback with “TTP” app

The first day of treatment:

1. Pass the ICIQ-SF questionnaire.
2. Develop Pad Test.
3. Pass the ISI questionnaire.
4. Perineometry assessment to measure muscle strength and to establish the treatment based on PERFECT results.

Duration of each session: There is not enough evidence about the duration of each physiotherapy therapy session, but analysing different systematic reviews, most of the studies established between 20 and 45 minutes so it will take on an average of 30 minutes each session (1,3,71).

Positions: lied, biped, kneeled, and sited with legs apart to emphasise specific strength of PFM's and relaxation of other pelvic muscles. Firstly, the patient will start the treatment lied, as the sessions go by and the contraction improves, the physiotherapist could consider other contraction positions (1).

Frequency: 3 times per week (1). It has been considered that three times per day will be too much in order to follow up the treatment adherence.

Duration: 2 weeks with the presence of the physiotherapist (P1) and then until 12 months without his/her presence to simulate they are training at home. Even though the study finishes at 12 months, once they have finished the study, it should be given a firmly recommendation to keep doing PFMT every day at home (1,70).

#### ✓ **EXPERIMENTAL GROUP**

- Pelvic Floor Muscle Training + biofeedback with "TTP" app
- Immersive Virtual Reality

The protocol will be the same as in the control group, the difference will be that the experimental group will perform the exercises through a sports-game using immersive virtual reality glasses with TTP app. The sport will first be chosen by the physiotherapist, based on the sport in which the patient competes to try to apply the acquired skills to the real competition. Once the contraction has improved, the patient can choose different games to practice.

The position, frequency and duration will be as in the Control group.

As it has been mentioned before on the "system characteristics", the TTP app allows connecting IVR or performing the exercise without IVR. In that way, it ensures that the same goals could be achieved with the Control and the Experimental group and so it allows to use the same application to develop the treatment in each group.

## 6 CALENDAR

STUDY PERIOD							
	Enrolment	Allocation	Post-allocation				Close-out
TIMEPOINT**	04/06/18-20/08/18	27/08/18	t <sub>1</sub> = 03/09/18	t <sub>2</sub> = 14/09/18	t <sub>3</sub> = 03/12/18	t <sub>4</sub> = 04/03/19	t <sub>5</sub> = 03/06/19
<b>ENROLMENT:</b>							
Eligibility screen	X						
Informed consent	X						
Anamnesis	X						
Allocation		X					
<b>INTERVENTIONS:</b>							
[Group A]			←→		←→		
[Group B]			←→		←→		
<b>ASSESSMENTS:</b>							
QUALITY OF LIFE	X		X		X		X
URINE LEAKAGE	X		X		X		X
INCONTINENCE SEVERITY	X		X		X		X
MUSCULAR STRENGTH	X		X		X		X
TREATMENT ADHERENCE			X		X	X	X

Table 4. Schedule of enrolment, interventions, and assessments SPIRIT (44).

With physiotherapist supervision ————  
 Without physiotherapist supervision ————

Analysis of the data, results and conclusions will be carried out 2 months after the end of the intervention.

## 7 LIMITATIONS AND BIAS

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Occasionally, limitations may arise that must be taken into account, as they could directly influence the final results of the project.

First of all, one of the basic restrictions of the project is the difficulty in meeting the number of participants that the project requires, since it is a pathology that is still somewhat "taboo" and patients have difficulties in accepting it, either by fear, by shame or simply because they do not consider it as an important pathology.

Another limitation is the possibility for patients to give up the intervention due to external causes. Although this fact is taken into account on the size of the sample, if there are more cessations, the results could be affected.

In the selection of the measurement tools of the project, it has been chosen those tools validated and used in numerous scientific studies and recommended by the European Association of Urology. However, there are disadvantages in the use of some selected measuring instruments, mainly due to the possibility of error in the measure between the different observers (physiotherapists). This is what happens in the case of the Perineometer. It is the most objective method that reports the scientific literature to assess muscle strength, but nevertheless, it has limitations in its use. Due to its shape (Figure 12. Peritron device), it is difficult to ensure the exact positioning of the perineometer because it is very sensitive to the movement and does not adhere to itself, requiring the physiotherapist to hold the utensil while evaluating the patient. After observing the bias in the use of the perineometer during my university clinical practice, as happens with biofeedback, a proposal future line could be the creation of a biofeedback catheter similar to the electro-stimulation one (*section 7.1*) to allow its use without having to be subjected.

It is necessary to point out that, as previously explained (*section 1.4*), that SUI may be due to either urethral hypermobility or intrinsic sphincter deficiency. In the first case, urethral hypermobility can be caused by a deficit in any of the supporting elements (muscles, ligaments, fascia, etc.). If the cause is muscle



Figure 13. Electrostimulation catheter (73).



weakness, the treatment will result effective. However, in the event that it is because of ligamentous or fascial weakness, it may be assumed that the fact of gaining strength with PFMT does not necessary correspond to the decrease in urine loss, since in these cases the specialist should be referred and assess the surgical intervention.

Finally it can be found bias of data collection, either because the patient provides us with incorrect information, forget information, subjectivity, confusion or mistrust, among others.

## 7.1 FUTURE INVESTIGATIONS

As mentioned above, the cylindrical structure of the BF/perineometer makes difficult to establish an exact assessment of perineal strength since the device is very sensitive to movement. After doing this project it is valued the idea of creating a BF with a similar structure to the vagina electrostimulation catheter probe that does not move.

In addition, there is no evidence to differentiate urethral hypermobility due to muscular weakness or any other support structure. It should be done more research in this field in order to derive from the first instance those patients that require the assessment of a specialist and/or surgical intervention. On the other hand, the relationship between the loss of urine and the deficit of strength has not been established either. It would be very beneficial to study this relationship to objectively assess the effectiveness of PFMT to set up adequate treatment objectives.

Furthermore, to date, there is no one standard questionnaire or test that fulfils all requirements for assessment of people with UI. Clinicians must evaluate the tools which exist, for use alone or in combination, for assessment and monitoring of treatment outcome (37).

The last future line proposed is to perform the qualitative study of how the treatment of the pathology could make changes in sports performance.

## 8 ETHICAL ASPECTCS AND DIFFUSION

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To ensure compliance with the applicable standards of research and human subjects, the IRBs / ECs [institutional review boards / ethical committees] will review and approve

this protocol and the informed consent form (*annex 12.6*), based on the Declaration of Helsinki (44,53).

All the information related to the study (participants' data, reports, data collection, processors and administrative forms) will be safely stored in the site of the study with files blocked in areas with limited access to the responsible researcher and the computer technician. The protocol has previously described on the Design and also the means by which personal information is collected and kept safe (*section 5.1*). The Data Management Coordination Centre will oversee the process of data exchange between studies, with the contribution of the Data Management Subcommittee (44,53).

## 8.1 ADVERSE EFFECTS

It will be classified as an adverse effect any symptom reported by the patient as: discomfort, soreness, pain, bleeding or any synonym. Cochrane systematic reviews do not report any adverse effect on their studies about PFMT treatment on SUI (3,9).

In the use of biofeedback, will be an adverse effect any event such as pelvic pain, vaginal or anal bleeding, skin reaction or muscle discomfort. Cochrane literature reports on a SR that only few women dropped out the treatment because of adverse events. It is surprising that 14 studies from the review does not report any measure of it. Although the adverse effects with regard to BF are minor and none of them seem to be serious, therapists should be careful because BF involves some vaginal or anal procedure (5).

About IVR, there is not literature about if there is any adverse effect on the use of this device to the treatment of SUI. However, the Cochrane systematic review "*Virtual reality for stroke rehabilitation*" reports few adverse effects across studies and those reported (transient dizziness, headache, and pain) were relatively mild (40).

However, before the participation, the patient will have to sign the informed consent in to guarantee that the subject has voluntarily expressed her intention to participate in the research, after having understood the information that has been given, about the objectives of the study, the benefits, the inconvenience, the possible risks and alternatives, their rights and responsibilities presented on a fact sheet (*annex 12.5*).

All participants enrolled, will have the right to be compensated in case of negligent damages. Compensation will be incurred through the National Health Service (NHS).

## 9 STUDY ORGANIZATION

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Researchers: They must comply with all the requirements of the protocol and they will be responsible for the accuracy and truth of the information obtained. Especially, they must ensure at all times for the best possible care of the patient.

Physiotherapist: They must attest that the information is true, for which they must have all kinds of facilities from the research team to develop their work. The physiotherapist (P1) will be the responsible for carrying out the treatment the first two weeks.

Evaluator: Will be an external physiotherapist (P2) to the investigation and will be assigned by the promoter. He/she will be the responsible to measure the requested variables on the dates established in the schedule (*section 6*) and note them on the date base “*Open Clinica*”.

Promoter: It is the University of Lleida and will be responsible for ensuring compliance with the relevant legal standards.

Monitoring procedures: Before initiating the study, in a meeting of researchers, a representative of the Promoter will review the protocol and the data collection notebooks with the researchers and other personnel involved in the study. During the study, the evaluator will visit the centre regularly, to compare the data collected and check adherence to the protocol and the Good Clinical Practice Guidelines. The investigator and trial staff should be available to assist the evaluator during these visits. No data revealing the identity of patients should leave the participating centre.

Audit: In addition to the monitoring procedures, the study may be audited by the Health Authorities (during the study or even when it has been completed), to assess compliance with the Good Clinical Practice standards. If a Health Authority requests an inspection, the investigator must immediately inform the Promoter that this request has been made.

## 9.1 RECORD OF DATA AND PRESERVATION OF DOCUMENTS

The researcher must complete the data collection notebooks provided by the Promoter and send the data as indicated at the beginning of the study. The data collected during the trial should be documented anonymously and dissociated, linked to a code (social security number), or to the initials of the patient if necessary, so that only the researcher can associate such data with an identified participant.

For approximately 2 months, all the data obtained in the measurements, computerized and classified in *Open Clinica* databases, will be analysed using statistical tools. Once the results have been obtained, based on tests such as hypothesis testing, the results will be discussed and a series of conclusions will be drawn about the initial hypotheses proposed.

The researcher will keep the original clinical documents of each patient of the study, which consist of all the medical and demographic information and a copy of the signed informed consent form, for at least 15 years after the conclusion or suspension of the study. By signing the protocol, the researcher agrees to follow the procedures for document preservation.

## 9.2 PUBLICATION CONDITIONS

The results of the study will be owned by the University of Lleida, who will establish a publication policy through a committee.

# 10 BUDGET

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To carry out the budget of the study, the resources have been divided into 3 groups:

- Facilities and HR.
- Material of Physiotherapy.
- Office supplies.

Table 5, 6 and 7 explain the expenses related to the human resources, to the physiotherapist' material and to the office material needed, as well as the facilities used.

<b>FACILITIES AND RRHH</b>	<b>UNITS</b>	<b>PRICE (€)</b>	<b>TOTAL</b>
<b>Local</b>	2	Ceded CAR Sant Cugat	-
<b>Physiotherapist who carry out the treatment</b>	4	7,63/h x 192	1.464,96
<b>Physiotherapist who process the results</b>	4	7,63/h x 96	732,48
<b>Evaluator researcher</b>	1	Voluntary	-
<b>Biostatistics specialist</b>	1	Ceded UdL	-
<b>Computer technician</b>	1	1.000/month x 12	12.000
<b>SUBTOTAL</b>	-	-	14.197,44 €

Table 5. Facilities and rrhh budget

<b>MATERIAL</b>	<b>UNITS</b>	<b>PRICE (€)</b>	<b>TOTAL</b>
<b>Litter</b>	32	Ceded UdL and Car Sant Cugat	-
<b>Litter paper</b>	3	Ceded UdL	-
<b>Exploration Gloves</b>	3	Ceded UdL	-
<b>Lubricating gel</b>	2	6,05/100g	12,10
<b>Condoms</b>	2	15,13 (pack 100)	30,26
<b>Cushions</b>	30	Ceded UdL and Car Sant Cugat	-
<b>Sanitary towels</b>	10	8,00 (pack 25)	80
<b>Room divider</b>	8	Ceded UdL	-
<b>Peritron (assessment)</b>	2	799,99/u	1.599,98
<b>Immersive virtual reality glasses</b>	2	200/u	400
<b>Immersive reality programme app</b>	1	Created by the computer technician	-
<b>BF with Bluetooth or Wi-Fi (treatment)</b>	4	800,00/u	3.200
<b>SUBTOTAL</b>	-	-	5.322,34 €

Table 6. Physiotherapist's material budget

<b>OFFICE MATERIAL</b>	<b>UNITS</b>	<b>PRICE (€)</b>	<b>TOTAL</b>
<b>Laptop</b>	2	445 €	890
<b>Open Clinica software</b>	1	Ceded by the computer technician	-
<b>Program SPSS</b>	1	Ceded by the biostatistics specialist	-
<b>SUBTOTAL</b>	-	-	890 €

Table 7. Office material budget

The sum of the 3 budget tables gives us a total of: 14.197,44 + 5.322,34 + 890 = 20.409,78 €

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## 12 ANNEX

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### 12.1 OPEN CLINICA

*Open Clinica* produces cloud software that accelerates the investigation labour. It is an electronic data capture and data management which allows study oversight and monitoring and engage patients on their own devices (45).

The platform does the randomization by its own and allows the researcher to choose whether a blinded or unblinded trial with unlimited treatment groups (45).

It is validated by the certified quality system ISO, SSAE -16, the European Medicines Agency and by Food and Drug Administration (45).

## 12.2 BASELINE SOCIODEMOGRAPHIC TABLE

<b>Characteristics</b>	<b>Group 1 (n= 32)</b>	<b>Group 2 (n=32)</b>
Age		
Body mass index (kg/m <sup>2</sup> )		
Height		
Weight		
Obstetric antecedents <ul style="list-style-type: none"> <li>- Number of pregnancies</li> <li>- Repeated urine infections</li> </ul>		
Pelvic surgical interventions		
Diseases: <ul style="list-style-type: none"> <li>- Diabetes</li> <li>- Connective tissue diseases</li> <li>- Depression</li> </ul>		
Smoking habit <ul style="list-style-type: none"> <li>- Yes</li> <li>- No</li> </ul>		
Hours per week of sport practice		
Type of sport practice <ul style="list-style-type: none"> <li>- High-impact</li> <li>- Low-impact</li> </ul>		
Medication <ul style="list-style-type: none"> <li>- Yes (which)</li> <li>- No</li> </ul>		
Constipation or cough symptoms <ul style="list-style-type: none"> <li>- Yes</li> <li>- No</li> </ul>		
Education <ul style="list-style-type: none"> <li>- University studies</li> <li>- Less than university studies</li> </ul>		

Table 8. Baseline sociodemographic characteristics (47,48).

## 12.3 UROGYNEACOLOGICAL ANAMNESIS

Pelvic Floor Pathway Clinic (address, phone number)			
PATIENT ASSESSMENT FORM			
<b>Stress Incontinence:</b> ___ yes ___ no ___ maybe	<input type="checkbox"/> cough <input type="checkbox"/> laugh <input type="checkbox"/> sneeze <input type="checkbox"/> running	<input type="checkbox"/> stairs <input type="checkbox"/> lifting <input type="checkbox"/> exercise <input type="checkbox"/>	<b>Frequency:</b> <input type="checkbox"/> rarely <input type="checkbox"/> weekly <input type="checkbox"/> daily <input type="checkbox"/> multiple times per day
<b>Urge Incontinence:</b> ___ yes ___ no ___ maybe	<input type="checkbox"/> with strong urge <input type="checkbox"/> upon waking <input type="checkbox"/> washing hands <input type="checkbox"/> hearing running water <input type="checkbox"/> key in door <input type="checkbox"/> standing	<input type="checkbox"/> enuresis	<b>Frequency:</b> <input type="checkbox"/> rarely <input type="checkbox"/> weekly <input type="checkbox"/> daily <input type="checkbox"/> multiple times per day
Urgency alone without Incontinence: ___ yes ___ no			
<b>UTI's:</b> ___ yes ___ no	<b>Per year:</b> <input type="checkbox"/> none <input type="checkbox"/> < 1	<input type="checkbox"/> 1 <input type="checkbox"/> 2-6 <input type="checkbox"/> > 6	<input type="checkbox"/> Pain with bladder filling <input type="checkbox"/> Pain with voiding
<b>Difficulty emptying:</b> ___ yes ___ no ___ maybe	<input type="checkbox"/> Straining <input type="checkbox"/> Double void <input type="checkbox"/> Hesitancy <input type="checkbox"/> Post void dribbling	Needs to push in prolapse to empty: <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> maybe Prolapse size affects emptying: <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> maybe	
<b>RED FLAG:</b> <input type="checkbox"/> visible hematuria	<input type="checkbox"/> microscopic <input type="checkbox"/> > 50 years old	<input type="checkbox"/> hematuria with UTI > 40 years old	
<b>Bowel function:</b>	<input type="checkbox"/> normal <input type="checkbox"/> loose	<input type="checkbox"/> constipation <input type="checkbox"/> alternating constipation & diarrhea	<b>Passage:</b> <input type="checkbox"/> easy <input type="checkbox"/> difficult <input type="checkbox"/> digitates vagina <input type="checkbox"/> digitates rectum
<b>Fecal Incontinence:</b> ___ yes ___ no ___ maybe	<b>Frequency:</b> <input type="checkbox"/> rare <input type="checkbox"/> < once per month <input type="checkbox"/> monthly <input type="checkbox"/> weekly <input type="checkbox"/> daily	<b>Incontinence suggestive of external sphincter (with urgency):</b> <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> maybe <b>Incontinence suggestive of internal sphincter (insensible losses, smearing):</b> <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> maybe	

Targetted questions for recurrent UTI

Targetted questions for difficulty emptying

Red flags indicate urgent referral

Targetted questions for fecal incontinence

Figure 14. Pre-appointment patient history

Pelvic Floor Pathway Clinic (address, phone number)						
PATIENT ASSESSMENT FORM						
Height:	Weight:				BMI:	
Saddle Sensation: S2/3/4 Light touch  Pin Prick	Right: <input type="checkbox"/> Nominal <input type="checkbox"/> Absent					
	Left: <input type="checkbox"/> Nominal <input type="checkbox"/> Absent					
	Right: <input type="checkbox"/> Nominal <input type="checkbox"/> Absent					
	Left: <input type="checkbox"/> Nominal <input type="checkbox"/> Absent					
Sacral Reflex:	<input type="checkbox"/> Bulbocavernosus <input type="checkbox"/> Anal wink					
Hysterectomy:	<input type="checkbox"/> yes <input type="checkbox"/> no					
Anterior	grade	0	1	2	3	
Apex	grade	0	1	2	3	
Posterior	grade	0	1	2	3	
Complete eversion:	<input type="checkbox"/> yes <input type="checkbox"/> no					
Post void residual:	<input type="checkbox"/> History of voiding difficulty <input type="checkbox"/> recurrent UTI <input type="checkbox"/> ≥ grade 2 cystocele or uterine prolapse <input type="checkbox"/> neurological disease on history		Measured by catheter: <input type="checkbox"/> <50ml <input type="checkbox"/> 50-100ml <input type="checkbox"/> >100ml  Measured by US: <input type="checkbox"/> <50ml <input type="checkbox"/> 50-100ml <input type="checkbox"/> >100ml			
RED FLAGS:	<input type="checkbox"/> Suspected pelvic or urinary tract mass		<input type="checkbox"/> Palpable bladder after voiding			
Pelvic Floor Strength	0	1	2	3	4	5
Introitus:	<input type="checkbox"/> normal <input type="checkbox"/> deficient					
Able to hold pessary:	<input type="checkbox"/> likely <input type="checkbox"/> unlikely					
TREATMENT OPTIONS						
Education	<input type="checkbox"/> Bladder Education <input type="checkbox"/> Caffeine avoidance <input type="checkbox"/> Urge suppression <input type="checkbox"/> Pelvic floor exercises					
Pessary	<input type="checkbox"/> Information re. Pessary <input type="checkbox"/> Pessary fitting					
Refer to physio						
Refer to GP	<input type="checkbox"/> Failed conservative therapy, wants meds <input type="checkbox"/> Information re. meds					
Refer to surgeon/ specialist	<input type="checkbox"/> Failed meds, wants surgery <input type="checkbox"/> Failed pessary, wants surgery <input type="checkbox"/> Has other gyne or urogyne complaints needing assessment					
Other:						

Targetted questions for neurogenic bladder/ neurological deficit

Targetted questions for difficulty emptying

Red flags indicate urgent referral

Indication for referral

Figure 15. Pelvic Floor Pathway Clinic

## 12.4 SUMMARY RECOMMENDATIONS

Red flag	Assessment	Referral
<b>Haematuria</b>	General assessment: <ul style="list-style-type: none"> <li>Do you see blood in your urine?</li> </ul>	Urologist
	Urinalysis <ul style="list-style-type: none"> <li>Red blood cells (unresolved after treatment for UTI, or after contributing factor has ceased)</li> </ul>	Urologist
	Urinalysis <ul style="list-style-type: none"> <li>Proteinuria, red cell casts, or dysmorphic red blood cells and/or an elevated creatinine</li> </ul>	Nephrologist
<b>Palpable bladder/ symptoms of incomplete emptying</b>	Abdominal exam <ul style="list-style-type: none"> <li>Percussible bladder</li> <li>Palpable bladder</li> <li>Tenderness/pain in bladder</li> </ul>	Urologist
	Post-void Catheterization <ul style="list-style-type: none"> <li>Residual volume &gt;150 ml</li> </ul>	Urologist
<b>Symptoms of neurogenic bladder</b>	Medical history <ul style="list-style-type: none"> <li>Neurologic disease</li> <li>Spinal trauma</li> <li>Diabetes</li> </ul>	further assessment
	Neurologic exam <ul style="list-style-type: none"> <li>Anal reflex</li> <li>Anal sphincter tone</li> <li>Saddle sensation</li> </ul>	Neurologist
<b>Pelvic Mass</b>	Urinalysis <ul style="list-style-type: none"> <li>Pregnancy test</li> </ul>	Gynaecologist
	Pelvic exam (including bi-manual) <ul style="list-style-type: none"> <li>Adenopathy</li> <li>Ascites</li> <li>Palpable mass</li> <li>Costovertebral Angle tenderness</li> <li>Compression of the cervix</li> <li>Adnexal or uterine enlargement</li> <li>Tenderness with vulvar or vaginal lesions</li> <li>Rectovaginal compression or blood in the rectum</li> </ul>	Gynaecologist

Table 9. Summary of Recommendations in UI assessment (51).

## 12.5 FACT SHEET FOR PATIENTS

**Title of the Study:** “The effectiveness of Pelvic Floor Muscle Training through Immersive Virtual Reality for the treatment of Stress Urinary Incontinence based on the impact on the quality of life in adult women elite athletes”

**Promotor:** Universidad de Lleida

### **Introduction:**

***Before you agree to participate in this study it is important that you read and understand the following information about the study and the procedures involved. If you have any questions about the study or your rights as a participant, do not hesitate to ask before taking your decision to participate.***

This document describes the objective, procedures, benefits, risks, discomforts and precautions involved in the study. Describes also the alternative treatments that are available to you and your rights as a participant. The results of the study cannot be guaranteed in any way.

It is essential that you be completely frank about your medical history and any other symptoms or reactions you may experience during the study. If not, you could injure yourself for your participation in the study. Participation in this research study is completely voluntary, and you can refuse to take part in or withdraw from the study at the time you want without affecting your future medical care. Below, you can find more detailed information. It is important that you read this consent document before making a decision about your participation.

### **Information on the background and objectives of the study:**

The Perineal Physiotherapy is a therapeutic discipline that allows to evaluate and treat pelvic floor dysfunctions (urinary and / or anal incontinence, perineal pain, prolapses, etc.) and others of the sexual sphere (dyspareunia, vaginismus, etc.) and that especially accompany to women in postpartum, menopause and man after prostate surgery.

You have been invited to participate in this clinical research study because you suffer from stress urinary incontinence as a result of a long and demanding sport practice, affecting your quality of life to a lesser or greater degree.



In this circumstance, it is essential to try to strengthen the pelvic floor musculature in order to improve your quality of life; and this is the objective to which the treatment was fundamentally addressed.

Like other physiotherapy specialties, perineal physiotherapy uses electrotherapy, biofeedback, manual techniques, perineal massage as a treatment, kinesiotherapy and behavioural techniques. Many of these procedures are intracavitary, that is to say they are intravaginal and/or ano/rectal. It should be done by specialized physiotherapists and with maximum hygiene guarantees, being intracavitary electrodes for individual use. The treatment does not guarantee the healing of the patient.

There are several methods for the treatment of stress urinary incontinence. However what is more recommended and scientifically proven is the pelvic floor muscle training (PFMT). Unfortunately, it is a treatment which seem to be hard to follow and patients tend to give it up.

The present study pretend to compare the effectivity of the PFMT with biofeedback and the addition of an immersive virtual reality (IVR) program in contrast to the conservative treatment (PFMT + biofeedback).

None of the treatments carried out in the present study include pharmacology.

**Objective:** Improve symptomatology and so the quality of life, and become aware of perineal muscles.

**Study procedure:**

Your participation in the study will last approximately 12 months.

If, after having read this document, you agreed to participate, you will be submitted to the following study procedures today:

- When all of your questions have been answered, you will be asked to write your name, sign and date this consent document.
- The type of treatment that corresponds to it will be chosen at random: PFMT + biofeedback or PFMT + biofeedback and IVR.

**Study risks:**

- Most of the techniques used in perineal physiotherapy have no adverse effects.

- Occasionally it may cause discomfort or pain because of the biofeedback.

You should warn the physiotherapist if you have a pacemaker implanted, suspected current infection or pregnancy, high blood pressure or any other process that may contraindicate the treatment. Will demand verbally how much information you need to understand.

**Benefits of participation in the study:**

You will not get any kind of benefit for participating in the study. However, the knowledge gained through your participation could help other people.

**Insurance / compensation:**

During your participation in the study, you will be covered by a civil liability policy contracted by the developer of the study that covers damages, as required by current Spanish legislation (RD223 / 2004).

**Confidentiality of information:**

Your identity, your hospital records and the information obtained in this trial are confidential, unless required by law, and will not be disclosed without your express written consent, to any person, except to the relevant staff of the study's promoters (University of Lleida), the Spanish health authorities and the clinical research ethics committee. If the results of this study are published, your identity will be kept confidential. By signing this document you are authorizing the researcher to provide your medical records related to your participation in the study, the sponsor, the relevant health authorities and the ethics committee. You can have direct access to the data and can request its revision according to the local legislation and procedures (Organic Law of December 13 Protection of Personal Data) of security measures of the automated data protection files.

**Voluntariness of participation:**

Participation in this research study is voluntary. You have the right to refuse to participate in the study or, if you participate, to withdraw from the study at any time, without affecting your future medical care. In addition, the investigator or the study sponsor may withdraw from the study without the need for consent, for any reason they

consider appropriate, such as, among others, an adverse effect that could place them at risk of further complications.

**Obtaining information:**

At any time you can ask the questions you want about the study. The investigator will provide you with his telephone number for any clarification. If during or after the study, you wish to discuss your participation in the study, or if you have any questions about the subjects of the research, your rights and/or about the injuries related to the study, you can contact....., researcher responsible for the study in the telephone number.....

## 12.6 INFORMED CONSENT FOR PATIENTS

**Title of the study:** “The effectiveness of Pelvic Floor Muscle Training through Immersive Virtual Reality for the treatment of the impact on the Quality of Life of adult women elite athletes with Stress Urinary Incontinence”

All data and personal documents will be stored and preserved with the utmost privacy and personal privacy complying with the Organic Law 15/1999, of December 13, Protection of Personal Data. Likewise, the director of the essay will be in charge of informing and answering all the doubts of the participants, as well as the way of contact in case of emergency or abandonment.

Me \_\_\_\_\_ with  
DNI \_\_\_\_\_

- I have read the information sheet that has been given to me
- I have been able to ask questions about the study
- I have received satisfactory answers to my questions
- I understand that my participation is voluntary
- I understand that I can withdraw from the study
  - When I want.
  - Without having to explain.
  - Without this having an impact on my medical care in any way.
  - I freely give my consent to participate in the study and I will receive a copy of this document.

Therefore, I freely give my consent to participate in the trial;

Barcelona, \_\_\_\_\_ Participant signature.

Barcelona, \_\_\_\_\_ Researcher signature.

## 12.7 ICIQ-SF

Número inicial

ICIQ-SF (versión española)

CONFIDENCIAL

Fecha de hoy      Día      Mes      Año

Hay mucha gente que en un momento determinado pierde orina. Estamos intentando determinar el número de personas que presentan este problema y hasta qué punto les preocupa esta situación. Le estaríamos muy agradecidos si nos contestase las siguientes preguntas, pensando en cómo se ha encontrado en las *últimas cuatro semanas*.

- Por favor, escriba la fecha de su nacimiento:
 

DÍA      MES      AÑO  
        
 Mujer ☐      Varón ☐
- Usted es (*señale cuál*):
- ¿Con qué frecuencia pierde orina? (*marque una*):
 

Nunca ☐ 0  
 Una vez a la semana o menos ☐ 1  
 Dos o tres veces a la semana ☐ 2  
 Una vez al día ☐ 3  
 Varias veces al día ☐ 4  
 Continuamente ☐ 5
- Nos gustaría saber su impresión acerca de la cantidad de orina que usted cree que se le escapa.  
 Cantidad de orina que pierde *habitualmente* (tanto si lleva protección como si no) (*marque uno*):
 

No se me escapa nada ☐ 0  
 Muy poca cantidad ☐ 2  
 Una cantidad moderada ☐ 4  
 Mucha cantidad ☐ 6
- Estos escapes de orina que tiene, ¿cuánto afectan su vida diaria?  
 (*por favor, marque un círculo en un número entre 0 –no me afectan nada– y 10 –me afectan mucho–*):
 

0      1      2      3      4      5      6      7      8      9      10

Nada      Mucho

Puntuación de ICI-Q: sume las puntuaciones de las preguntas.    3 + 4 + 5 =
- ¿Cuándo pierde orina? (*señale todo lo que le pasa a usted*):
 

Nunca pierde orina ☐  
 Pierde orina antes de llegar al WC ☐  
 Pierde orina cuando tose o estornuda ☐  
 Pierde cuando duerme ☐  
 Pierde orina cuando hace esfuerzos físicos/ejercicio ☐  
 Pierde orina al acabar de orinar y ya se ha vestido ☐  
 Pierde orina sin un motivo evidente ☐  
 Pierde orina de forma continua ☐

Muchas gracias por contestar estas preguntas.

Figure 16. International Consultation on Incontinence Questionnaire (50,54).

## 12.8 PAD TEST 1H

PAD TEST 1 HOUR		
Time	Physiotherapist work	Patient work
0 minutes	Sanitary towel weight	500 ml liquid without Na
30 minutes		Walk and go up stairs
45 minutes		Stand up the chair x10 Cough x10 Run 1 minute Catch objects from the floor x5 Handwashing 1 minute
60 minutes	Sanitary towel weight	

Table 10. Pad test 1 hour standardization (72).

## 12.9 INCONTINENCE SEVERITY INDEX

English	Spanish
<i>How often do you experience urinary leakage?</i>	<i>¿Con que frecuencia se le escapa la orina?</i>
1. Less than once a month	1. Menos de una vez al mes
2. A few times a month	2. Algunas veces al mes
3. A few times a week	3. Algunas veces a la semana
4. Every day and/or night	4. Todos los días y/o noches
<i>How much urine do you lose each time?</i>	<i>¿Qué cantidad de orina se le escapa cada vez?</i>
1. Drops	1. Gotas (muy poca cantidad)
2. Small splashes	2. Chorro pequeño (una cantidad moderada)
3. More	3. Mucha cantidad

The severity index is created by multiplying the results of the two questions, and then categorizing it as follows: 1–2=slight, 3–6=moderate, 8–9=severe, 12=very severe  
For statistical purposes in follow-up studies, we recommend adding the value 0 (zero) for those who become continent

Figure 17. Incontinence severity index questionnaire (58).

## 12.10 EAU RECOMMENDATIONS

Recommendations	GR
Offer supervised intensive PFMT, lasting at least 3 months, as a first-line therapy to women with stress urinary incontinence or mixed urinary incontinence.	A
PFMT programmes should be as intensive as possible.	A
Offer PFMT to elderly women with urinary incontinence.	B
Consider using biofeedback as an adjunct in women with stress urinary incontinence.	A
Offer instruction on PFMT to men undergoing radical prostatectomy to speed recovery of incontinence.	B
Offer bladder training as a first-line therapy to adults with urgency urinary incontinence or mixed urinary incontinence.	A
Use a trial of prompted voiding for adults with incontinence, who are cognitively impaired.	A
Do not offer electrical stimulation with surface electrodes (skin, vaginal, anal) alone for the treatment of stress urinary incontinence.	A
Consider offering electrical stimulation as an adjunct to behavioural therapy in patients with urgency urinary incontinence.	B
Do not offer magnetic stimulation for the treatment of incontinence or overactive bladder in adult women.	B
Do not offer PTNS to women or men who are seeking a cure for urgency urinary incontinence.	A
Offer, if available, P-PTNS as an option for improvement of urgency urinary incontinence in women who have not benefitted from antimuscarinic medication.	B
Support other healthcare professionals in use of rehabilitation programmes including prompted voiding for care of elderly care-dependent people with urinary incontinence.	A

*PFMT = pelvic floor muscle training; P-PTNS = percutaneous posterior tibial nerve stimulation; T-PTNS = transcutaneous posterior tibial nerve stimulation.*

Figure 18. EAU Recommendations for behavioural and physical therapies (37).